```
  * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *
FILE 'USPAT' ENTERED AT 16:57:36 ON 23 AUG 1999

  * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *
  *         U. S.   P A T E N T   T E X T   F I L E                     *
  *                                                                     *
  *  THE WEEKLY PATENT TEXT AND IMAGE DATA IS CURRENT                   *
  *  THROUGH AUGUST 17,1999                                  *          *
  *                                                                     *
  *                                                                     *
  * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *

=> s stent and graft and (adhere? or glue?) and (tape or ribbon)

         1964 STENT
        26533 GRAFT
       189256 ADHERE?
        61132 GLUE?
       144952 TAPE
        38426 RIBBON
L1          37 STENT AND GRAFT AND (ADHERE? OR GLUE?) AND (TAPE OR RIBBON)

=> d l1 1-37 pn

US PAT NO:     5,928,279 [IMAGE AVAILABLE]          L1: 1 of 37
US PAT NO:     5,925,075 [IMAGE AVAILABLE]          L1: 2 of 37
US PAT NO:     5,855,598 [IMAGE AVAILABLE]          L1: 3 of 37
US PAT NO:     5,849,035 [IMAGE AVAILABLE]          L1: 4 of 37
US PAT NO:     5,833,650 [IMAGE AVAILABLE]          L1: 5 of 37
US PAT NO:     5,833,593 [IMAGE AVAILABLE]          L1: 6 of 37
US PAT NO:     5,824,046 [IMAGE AVAILABLE]          L1: 7 of 37
US PAT NO:     5,824,043 [IMAGE AVAILABLE]          L1: 8 of 37
US PAT NO:     5,817,126 [IMAGE AVAILABLE]          L1: 9 of 37
US PAT NO:     5,810,870 [IMAGE AVAILABLE]          L1: 10 of 37
US PAT NO:     5,797,933 [IMAGE AVAILABLE]          L1: 11 of 37
US PAT NO:     5,755,777 [IMAGE AVAILABLE]          L1: 12 of 37
US PAT NO:     5,741,323 [IMAGE AVAILABLE]          L1: 13 of 37
US PAT NO:     5,735,892 [IMAGE AVAILABLE]          L1: 14 of 37
US PAT NO:     5,720,776 [IMAGE AVAILABLE]          L1: 15 of 37
US PAT NO:     5,718,973 [IMAGE AVAILABLE]          L1: 16 of 37
US PAT NO:     5,700,285 [IMAGE AVAILABLE]          L1: 17 of 37
US PAT NO:     5,693,084 [IMAGE AVAILABLE]          L1: 18 of 37
US PAT NO:     5,662,712 [IMAGE AVAILABLE]          L1: 19 of 37
US PAT NO:     5,639,278 [IMAGE AVAILABLE]          L1: 20 of 37
US PAT NO:     5,628,786 [IMAGE AVAILABLE]          L1: 21 of 37
US PAT NO:     5,562,726 [IMAGE AVAILABLE]          L1: 22 of 37
US PAT NO:     5,549,663 [IMAGE AVAILABLE]          L1: 23 of 37
US PAT NO:     5,486,593 [IMAGE AVAILABLE]          L1: 24 of 37
US PAT NO:     5,412,068 [IMAGE AVAILABLE]          L1: 25 of 37
US PAT NO:     5,387,235 [IMAGE AVAILABLE]          L1: 26 of 37
US PAT NO:     5,370,691 [IMAGE AVAILABLE]          L1: 27 of 37
US PAT NO:     5,274,074 [IMAGE AVAILABLE]          L1: 28 of 37
US PAT NO:     5,256,764 [IMAGE AVAILABLE]          L1: 29 of 37
US PAT NO:     5,185,408 [IMAGE AVAILABLE]          L1: 30 of 37
US PAT NO:     5,152,781 [IMAGE AVAILABLE]          L1: 31 of 37
US PAT NO:     5,145,945 [IMAGE AVAILABLE]          L1: 32 of 37
US PAT NO:     5,108,407 [IMAGE AVAILABLE]          L1: 33 of 37
US PAT NO:     5,066,772 [IMAGE AVAILABLE]          L1: 34 of 37
US PAT NO:     4,920,203 [IMAGE AVAILABLE]          L1: 35 of 37
US PAT NO:     4,916,193 [IMAGE AVAILABLE]          L1: 36 of 37
US PAT NO:     4,202,331 [IMAGE AVAILABLE]          L1: 37 of 37
```

=> d 1-37 kwic

US PAT NO: 5,928,279 [IMAGE AVAILABLE] L1: 1 of 37

ABSTRACT:
Stented . . . present invention include an integrally stented embodiment, an externally stented embodiment, and an internally stented embodiment. In each embodiment, the stent may be either self-expanding or pressure-expandable. Also, in each embodiment, the stent may be coated or covered with a plastic material capable of being affixed (e.g., heat fused) to PTFE. Manufacturing methods. . . on a mandrel and are subsequently heated to facilitate attachment of the PTFE layer(s) to one another and/or to the stent. Optionally, the stented graft may be post-flexed and post-expanded following it's removal from the mandrel to ensure that the stented graft will be freely radially expandable and/or radially contractible over it's full intended range of diameters.

SUMMARY:

BSUM(5)

The . . . collapsed state suitable for transluminal insertion via a delivery catheter, and subsequently transitioned to a radially expanded state whereby the stent will contact and engage the surrounding wall or the anatomical duct or body cavity within which the stent has been positioned. Such stents have been used to support and maintain the patency of blood vessel lumens (e.g., as. . . as a tubular endovascular grafts, at desired locations within a body cavity or passageway (e.g., to anchor a tubular endovascular graft within a blood vessel such that the graft forms an internal conduit through an aneurysm or site of traumatic injury to the blood vessel wall).

SUMMARY:

BSUM(8)

Self-expanding . . . self-expanding to it's fully radially expanded configuration without the need for the exertion of outwardly directed radial force upon the stent by some extraneous expansion apparatus (e.g., a balloon or mechanical expander tool). These self-expanding stents may be initially radially compressed. . . or alternatively mounted upon the outer surface of a delivery catheter equipped with some means for restraining or maintaining the stent in it's radially compressed state. Thereafter, the delivery catheter is inserted into the body and is advanced to a position where the stent is located at or near the site at which it is to be implanted. Thereafter, the stent is expelled out of (or released from) the delivery catheter and allowed to self-expand to it's full radial diameter. Such expansion of the stent causes the stent to frictionally engage the surrounding wall of the body cavity or passageway within which the stent has been positioned. The delivery catheter is then extracted, leaving the self-expanded stent at it's intended site of implantation. Some examples of self-expanding stents of the prior art include those described in U.S.. . .

SUMMARY:

BSUM(10)

The . . . of metal wire, metal strips, or other malleable or plastically deformable material, fabricated into a generally cylindrical configuration. The pressure-expandable stent is initially disposed in a collapsed configuration having a diameter which is smaller than the desired final diameter of the stent, when implanted in the blood vessel. The collapsed stent is then loaded into or mounted upon a small diameter delivery catheter. The delivery catheter is then advanced to its desired location within the vasculature, and a balloon or other stent-expansion apparatus (which may be formed integrally of or incorporated into the delivery catheter) is utilized to exert outward radial force on the stent, thereby radially expanding and plastically deforming the stent to it's intended operative diameter whereby the stent frictionally engages the surrounding blood vessel wall. The material of the stent undergoes plastic deformation during the pressure-expansion process. Such plastic deformation of the stent material causes the stent to remain in its radially expanded operative configuration. The balloon or other expansion apparatus is then deflated/collapsed and is withdrawn from the body separately from, or as part of, the delivery catheter, leaving the pressure-expanded stent

at it's intended site of implantation.

SUMMARY:

BSUM(14)

The . . . surgical techniques, whereby a diseased or damaged segment of blood vessel is surgically excised and removed, and the tubular bioprosthetic graft is then anastomosed into the host blood vessel as a replacement for the previously removed segment thereof. Alternatively, such tubular prosthetic vascular grafts have also been used as bypass grafts wherein opposite ends of the graft are sutured to a host blood vessel so as to form a bypass conduit around a diseased, injured or occluded. . .

SUMMARY:

BSUM(15)

In . . . have been formed of extruded, porous PTFE tubes. In some of the tubular grafts of the prior art a PTFE tape is wrapped about and laminated to the outer surface of a tubular base graft to provide reinforcement and additional burst strength. Also, some of the prior tubular prosthetic vascular grafts have included external support member(s) such as a PTFE beading, bonded or laminated to the outer surface of the tubular graft to prevent the graft from becoming compressed or kinked during implantation. These externally supported tubular vascular grafts have proven to be particularly useful for. . .

SUMMARY:

BSUM(16)

One commercially available, externally-supported, tubular vascular graft is formed of a PTFE tube having a PTFE filament helically wrapped around, and bonded to, the outer surface of the PTFE tube. (IMPRA Flex.TM. Graft, IMPRA, Inc., Tempe, Ariz.).

SUMMARY:

BSUM(17)

One other commercially available, externally-supported, tubular vascular graft comprises a regular walled, PTFE tube which has PTFE reinforcement tape helically wrapped around, and bonded to, the outer surface of the PTFE tube and individual rings of Fluorinated Ethylene Propylene (FEP) rings disposed around, and bonded to, the outer surface of the reinforcement tape. (FEP ringed ePTFE vascular graft, W. L. Gore & Associates, Inc., Flagstaff, Ariz.).

SUMMARY:

BSUM(19)

The prior art has also included a number of "stented grafts". These stented grafts typically comprise a self-expanding or pressure-expandable stent which is affixed to or formed within a pliable tubular graft. Because of their radial compressibility/expandability, these stented grafts are particularly useable in applications wherein it is desired to insert the graft into an anatomical passageway (e.g., blood vessel) while the graft is in a radially compact state, and to subsequently expand and anchor the graft to the surrounding wall of the anatomical passageway.

SUMMARY:

BSUM(20)

More . . . lumen of a blood vessel, by percutaneous or minimal incision means. Such endovascular implantation initially involves translumenal delivery of the graft, in a compacted state, by way of a catheter or other transluminally advancable delivery apparatus. Thereafter, the graft is radially expanded and anchored to the surrounding blood vessel wall, thereby holding the graft at its intended site of implantation within the host blood vessel. An affixation apparatus such as a stent, is typically utilized to anchor at least the opposite ends of the tubular graft to the surrounding blood vessel wall. One particular application for endovascular grafts of this type is in the treatment of. . . blood vessel. Also, such stented grafts may also be useable to treat occlusive vascular disease--especially in cases where the stented graft is constructed in such a manner that the tubular graft material forms a complete barrier between the stent and the blood which is flowing through the blood vessel. In this manner the tubular graft material may serve as a smooth, biologically compatible, inner "covering" for the stent, thereby preventing a) turbulent blood-flow as the blood flows over the wire members or other structural material of which the stent is

formed, b) immunologic reaction to the metal or other material of which the stent is formed, and c) a barrier to separate a diseased or damaged segment of blood vessel from the blood-flow passing therethrough. Such prevention of turbulent blood-flow and/or immunologic reaction to the stent material is believed to be desirable as both of these phenomena are believed to be associated with thrombus formation and/or. . .

SUMMARY:

BSUM(22)

Many . . . the stented grafts known in the prior art have utilized woven or knitted material, such as polyester fiber, as the graft material.

SUMMARY:

BSUM(23)

There exists a need for the development of a radially expandable, stented graft formed of a continuous, tubular ePTFE tube because the inherent properties of PTFE may offer various clinical advantages over the woven polyester and other graft materials which have been previously used in stented grafts of the prior art.

SUMMARY:

BSUM(25)

The . . . of manufacture. In general, the present invention may exist in any of three (3) separate embodiments, depending upon whether the stent component of the graft is formed integrally (i.e., within) the tubular PTFE graft, externally (i.e., on the outer surface of) the tubular PTFE graft, or internally (i.e., on the inner lumenal surface) of the PTFE tubular graft. Each of these three separate embodiments of the invention may be self expanding (i.e., incorporating a self-expanding stent) or pressure-expandable (i.e., incorporating a pressure-expandable stent.

SUMMARY:

BSUM(26)

In accordance with a first embodiment of the invention, there is provided an integrally stented PTFE graft which comprises a tubular PTFE base graft preferably of a density less than 1.6 g/cc, a radially expandable stent surrounding the outer surface of the tubular base graft, and an outer PTFE layer having a density of less than 1.6 g/cc. The tubular outer layer is fused to the tubular base graft through lateral openings or perforations formed in the stent. A polymer coating, such as a PTFE coating, may be disposed on the stent to further facilitate fusing or boding of the stent to the base tube and/or outer tubular layer.

SUMMARY:

BSUM(27)

In accordance with a second embodiment of the invention, there is provided an externally stented, tubular PTFE graft which comprises a radially compressible/expandable stent having a ePTFE tube of less than 1.6 g/cc density coaxially disposed within the stent, with the outer surface of the tubular ePTFE graft being fused or attached to the stent. A polymer coating, such as PTFE or any other plastic which may be fused or adhered to PTFE, may be applied to or formed on the stent to facilitate the desired fusion or attachment of the tube graft to the stent, and/or to improve the biocompatibility of the stent.

SUMMARY:

BSUM(28)

In accordance with a third embodiment of the invention, there is provided an internally stented, tubular PTFE graft comprising a tubular outer layer formed of ePTFE having a density of less than 1.6 g/cc, and a radially expandable stent. The stent is coaxially disposed within the lumen of the tubular outer layer, and fused or attached thereto. The stent may be covered with a polymer coating, such as PTFE or other biocompatable plastic capable of adhering or fusing to PTFE, to facilitate the desired fusion or attachment of the stent to the outer tubular layer, and/or to improve the biocompatability of the stent. Additionally or alternatively, PTFE particles may be disposed between the tubular outer layer and the tubular base graft to facilitate adhering or fusing of these two layers to one another, and/or to the stent. Such PTFE particles may be disposed between the inner

base graft and outer tubular layer by applying or depositing PTFE liquid dispersion therebetween, or by depositing dry PTFE resin powder therebetween.

SUMMARY:

BSUM(29)

Any . . . of the invention may be manufactured by a method which comprises the steps of: a) initially positioning a generally cylindrical stent of either the self-expanding or pressure-expandable variety in contacting coaxial relation with the tubular ePTFE base graft and/or the tubular ePTFE outer layer, upon a cylindrical mandrel or other suitable support surface, and b) subsequently fusing the fuse (i.e., heating to a lamination temperature) assembled components (i.e., the stent in combination with the inner base graft and/or outer tubular layer) of the stented graft into a unitary stented graft structure. In integrally stented embodiments where both the tubular ePTFE base graft and the tubular ePTFE outer layer are present, such heating will additionally cause the tubular outer layer to fuse to the inner tubular base graft, through lateral openings or perforations which exist in the stent. The stent may be surface treated, abraded, or coated with a plastic capable of adhering or fusing to ePTFE to facilitate attachment of the stent to the adjacent outer layer and/or inner base graft upon subsequent heating, application of solvent or other suitable adhesion promoting technique. In instances where a plastic coating is formed on the stent, such coating may be in the nature of a tube or film which is applied to the stent prior to assembly and mounting of the stented graft components on the mandrel or other support surface. Also, in embodiments where both the outer tubular layer and tubular base graft are used, aqueous PTFE dispersion, powdered PTFE resin or other flowable plastic material, may be deposited between the outer tubular layer and inner tubular base graft at the time of assembly (prior to heating) to further facilitate fusion of the outer tubular layer and/or inner tubular base graft to the stent and/or to one another.

SUMMARY:

BSUM(30)

By . . . of the present invention are capable of radially expanding and contracting without excessive puckering, wrinkling or invagination of the PTFE graft material. Furthermore, in embodiments wherein the stent is constructed of individual members which move or reposition relative to one another during respective expansion and contraction of the stented graft, the manufacturing methods and materials of the present invention render the PTFE sufficiently strong and sufficiently firmly laminated or fused so as to permit such relative movement of the individual members of the stent without tearing or rupturing of the tubular PTFE graft.

DRAWING DESC:

DRWD(2)

FIG. 1 is a perspective view of an integrally stented PTFE tubular graft of the present invention, wherein a portion of the graft has been inserted into a tubular catheter.

DRAWING DESC:

DRWD(4)

FIG. 2 is an enlarged, cut-away, elevational view of a preferred, integrally stented, tubular PTFE graft of the present invention.

DRAWING DESC:

DRWD(5)

FIG. 3a is an enlarged perspective view of a portion of the stent incorporated in the graft of FIG. 2.

DRAWING DESC:

DRWD(7)

FIGS. 4a-4f are a step-by-step illustration of a preferred method for manufacturing an integrally stented PTFE graft of the present invention.

DRAWING DESC:

DRWD(8)

FIG. . . . is a schematic illustration of an alternative electron

beam deposition method which is usable for depositing PTFE coating on the stent portion of the integrally stented PTFE grafts of the present invention.

DETDESC:

DETD(3)
A. The Structure of an Integrally Stented PTFE Graft

DETDESC:

DETD(4)

With reference to FIGS. 1-3b, there is shown an integrally stented tubular PTFE graft 10 of the present invention. The preferred integrally stented graft 10 comprises a tubular PTFE base graft 12, a PTFE-coated stent 14 and an outer layer of PTFE 16.

DETDESC:

DETD(5)

One of the many types of stents which may be used to form the stent 14 component of a stented graft 10 of the present invention, is shown in the drawings. This particular stent 14 is formed of individual elements or wires 18 which have been coated with a PTFE coating 20. Gaps or. . . lateral openings 19 exist between adjacent ones or bundles of the wires 18. The configuration, construction, and function of this stent 14 is described in detail in U.S. Pat. Nos. 4,655,771 Wallsten); 4,954,126 (Wallsten); and 5,061,275 (Wallsten et al.), the entireties. . . of which are hereby expressly incorporated herein by reference. As shown in the figures of this patent application, this particular stent 14 is composed of rigid but resiliently flexible thread elements or wires 18. These thread elements or wires 18 are. . . iron. One specific example of a commercially available alloy which may is usable to form the wires 18 of the stent 14 is Elgiloy (The Elgiloy Company, 1565 Fleetwood Drive, Elgin, Ill. 60120). The wires 18 of this stent 14 are arranged in helical configuration about a common longitudinal axis LA. A number of the wires 18 are positioned. . . of adjacent ones of the wires wound in the first helical direction so as to form a helically braided wire stent as shown in the Figures. This results in the formation of a braided wire stent 14 of generally tubular configuration which is self-expanding and biased to it's radially expanded diameter D.sub.2. However, this stent 14 may be radially compressed to a smaller diameter D.sub.1 and radial constraint, as may be applied by the surrounding wall of the tubular delivery catheter 22 shown in FIG. 1, may be applied to hold the stent 14 in such radially compressed state (diameter D.sub.1). Thereafter, when the radial constraint is removed from the stent 14, the stent 14 will resiliently spring back to its radially expanded diameter D.sub.2. The individual, helically wound wires 18 of this particular braided stent 14 move and articulate such that the angular dispositions of the wires 18, relative to one another, will change radial expansion and compression of the stent 14. Also, the longitudinal length of the stent 14 will increase as the stent 14 is radially compressed toward its radially compact configuration D.sub.1, and such length will shorten as the stent 14 expands toward its radially expanded configuration D.sub.2. Thus, the optional PTFE coating 20 is applied to the wires 18 of the stent 14, such coating (described in detail herebelow) is preferably flexible enough to withstand the flexing and movement of the individual. . .

DETDESC:

DETD(6)

The tubular base graft 12 is initially coaxially positioned within the hollow inner bore of the tubular stent 14 while the stent 14 is in its radially expanded configuration, after the stent 14 has been coated with the PTFE coating 20, if desired. Thereafter, the outer PTFE layer 16 is formed by any suitable means, such as by wrapping PTFE tape 17 upon the outer surface of the PTFE coated stent 14 to form the generally tubular outer PTFE layer 16. Thereafter, heat or other means are utilized to fuse the outer PTFE layer 16 to the inner base graft 12, through the gaps or openings 19 which exist in the stent 14. In embodiments wherein the optional PTFE coating 20 has been applied to the stent 14, such heating will also facilitate bonding of the PTFE coating 20 of the stent 14 to the adjacent base graft 12 and outer PTFE layer 16. In this manner, there is formed a self-expanding, tubular, integrally stented, PTFE graft 10 of substantially unitary constructions. The stent 14 forms an integral structural framework within the tubular graft 10, and the fused PTFE body of the graft is low enough in density and sufficiently pliable to allow the stent 14 incorporated into the graft 10 to continue to undergo substantially the same range of radial expansion and contraction that such stent 14 was capable of before disposition of the PTFE graft thereon. In this regard, the internally stented

graft 10 is radially compressible to the stent's first diameter D.sub.1 and may be may be inserted into the lumen of a small diameter tubular catheter 22. The external constraint provided by the wall of the catheter 22 will maintain the stented graft 10 in it's radially compressed configuration of diameter D.sub.1 until such time as the graft 10 is expelled or ejected out of the catheter 22. After the graft 10 has been expelled or ejected out of the catheter 22, the graft will self-expand to a diameter which is substantially equal to the original expanded diameter D.sub.2 of the stent 14.

DETDESC:

DETD(7)
B. Preparation of the Tubular Base Graft

DETDESC:

DETD(9)

The manufacture of the tubular base graft begins with the step of preparing a PTFE paste dispersion for subsequent extrusion. This PTFE paste dispersion may be prepared. . .

DETDESC:

DETD(16)

Preferably, the base graft 12 is formed of expanded, sintered PTFE having a density of less than 1.6 grams per cubic centimeter.

DETDESC:

DETD(19)

Completion of the sintering step marks the completion of the preparation of the expanded, sintered PTFE base graft 12.

DETDESC:

DETD(20)

The PTFE tape 16 may be manufactured by any suitable method, including the general method for manufacturing expanded PTFE tape, as follows:

DETDESC:

DETD(21)
C. Preparation of PTFE Tape

DETDESC:

DETD(23)

The usual manufacture of an expanded, sintered PTFE tape 17 useable to form the outer PTFE layer 16 of the stented graft 10 begins with the preparation of a PTFE paste dispersion. This PTFE paste dispersion may be prepared in the same manner as described hereabove for preparation of the PTFE paste dispersion used to form the tubular base graft.

DETDESC:

DETD(37)

After . . . is cut into strips, each strip typically having a width of 0.25-0.50 inches, thereby creating strips of expanded, sintered PTFE tape 14.

DETDESC:

DETD(38)
D. Coating of the Stent and/or Deposition of PTFE Between Layers to Enhance Bonding

DETDESC:

DETD(39)

Prior to assembly of the components of the integrally stented graft 10, the stent 14 may be coated with a polymer coating 20.

DETDESC:

DETD(40)

The polymer coating formed on the stent 14 may be any suitable type of polymer which will adhere to PTFE. Examples of polymers which may

be used for such polymer coating or covering include polytetrafluoroethylene (PTFE), fluorinated ethylene. . .

DETDESC:

DETD(41)

One manner in which such coating of the stent 14 may be carried out is illustrated in FIG. 4a. As shown in FIG. 4a, the stent 14 may be immersed in a vessel 30 containing an aqueous dispersion of PTFE 32. One aqueous PTFE dispersion which may be useable for coating of the stent 14 is DuPont T-30 Aqueous PTFE Dispersion, available commercially from the E.I. DuPont de Numoris Co., (Wilmington, Del.). Another commercially available PTFE dispersion 32 which may be utilized for coating of the stent is Daikin-Polyflon TFE Dispersion, available from Daikin Industries, Ltd., Chemical Division (Umeda Center Bldg., 4-12 chome, Nakazaki-nishi, Kita-ku, Osaka, Japan).

DETDESC:

DETD(42)

The time in which the stent 14 must remain immersed in the liquid PTFE dispersion 32 may vary, depending on the construction of the stent 14 and the chemical composition of the PTFE dispersion 32. However, in most cases, an immersion time of 10-15 seconds will be sufficient to obtain uniform deposition of the PTFE coating 20 on the wire members 18 of the stent 14.

DETDESC:

DETD(43)

After the stent 14 has been removed from the liquid PTFE dispersion 32 it will be permitted to air dry such that a dry PTFE coating 20 remains deposited upon the outer surface of each wire 18 of the stent 14.

DETDESC:

DETD(44)

Optionally, after the air drying has been completed, the PTFE coated stent 14 may be placed in an oven at 350.degree. C. for approximately 10 minutes to sinter the PTFE coating and/or to enhance the bonding of the PTFE coating 20 to wire members 18 of the stent 14. Sintering of the PTFE coating renders the coating more resistant to abrasion or peeling during the subsequent handing of the stent and/or the ensuing manufacture and use of the stented graft 10. It will be appreciated that various alternative methods, other than immersion, may be used for depositing the PTFE coating 20 on the stent 14. One alternative method is electron beam deposition, as illustrated in FIG. 5. In accordance with this alternative PTFE deposition method, the stent 14 is positioned within a closed vacuum chamber 36 wherein a mass of PTFE 38 is located. An electron beam. . . cause sublimation of the PTFE and resultant deposition of the layer 20 of PTFE on the outer surface of the stent 14. The apparatus and specific methodology useable to perform this electron beam deposition of the PTFE coating 20 are well. . .

DETDESC:

DETD(45)

As with the above-described immersion process (FIG. 4a), the stent 14 whereupon the PTFE coating 20 has been deposited may be subjected to optional heating at 350.degree. C. for a. . . the PTFE coating and/or to enhance the bonding of the PTFE coating 20 to the wire members 18 of the stent 14.

DETDESC:

DETD(46)

As an alternative to coating of the stent, or in addition thereto, such PTFE aqueous dispersion may be painted onto the outer surface of the base graft 12, or the inner surface of the outer tubular layer 16, or may be otherwise disposed between the base graft 12 and outer tubular layer 16 to facilitate fusion or bonding of the inner base graft 12 to the outer tubular layer 16. Or, such PTFE aqueous dispersion may be sprayed or otherwise applied to the. . . pores in the outer tubular layer 16, thereby becoming deposited between the outer tubular layer 16 and the inner base graft 12.

DETDESC:

DETD(47)

Another alternative or additional means by which adherence or fusion of the base graft 12, outer tubular layer 16 and/or stent 14 may be facilitated or enhanced includes the deposition of raw PTFE resin powder between the outer tubular layer 16 and inner base graft 12, and/or upon the stent 14.

DETDESC:

DETD(48)

It will be appreciated that in many cases, it will be desirable to apply the polymer coating 20 to the stent 14 while the stent 14 is in it's fully radially expanded configuration of diameter D.sub.2. In this manner, after the coating 20 has been applied and formed on the fully radially expanded stent 14, the stent 14 may subsequently be contracted to it's radially compact configuration of diameter D.sub.1 without tearing or disrupting of the previously-applied coating 20. In embodiments which utilize a pressure-expandable stent 14, it may thus be necessary to volitionally or purposely expand the stent 14 to it's fully radially expanded diameter D.sub.2 prior to application of the coating 20. Alternatively, when the stent 14 is of the self-expanding variety it will, in most cases, automatically assume it's fully radially expanded configuration of diameter D.sub.2 and no such volitional or purposeful pre-expansion of the stent 14 will be required.

DETDESC:

DETD(49)

The . . . which liquid PTFE dispersion and/or solid PTFE powder may be deposited between the outer tubular layer 16, and inner base graft 12 will be discussed in more detail herebelow with reference to the manufacturing methodology.

DETDESC:

DETD(50)
E. Assembly and Construction of the Integrally Stented PTFE Graft

DETDESC:

DETD(51)

FIGS. 4b-4f show, in step-wise fashion, the preferred method for assembling and constructing the integrally stented PTFE graft 10.

DETDESC:

DETD(52)

As shown in FIG. 4b, the tubular base graft 12 is initially disposed on a rod or mandrel 50. Such rod or mandrel 50 may comprise a stainless steel rod having an outer diameter which is only slightly smaller than the inner diameter of the tubular base graft 12. In this manners the tubular base graft 12 may be slidably advanced onto the outer surface of the mandrel 50 without undue effort or damage to the base graft 12.

DETDESC:

DETD(53)

Thereafter, the PTFE-coated stent 14 is axially advanced onto the outer surface of the tubular base graft 12, as shown in FIG. 4c.

DETDESC:

DETD(54)

At this point in the process, PTFE liquid dispersion or powdered PTFE resin may be additionally (optionally) applied to the stent 14 and/or outer surface of the base graft 12 to promote further bonding and fusion of the base graft 12 to the stent 14 and/or subsequently applied outer layer 16. In this regard, the mandrel-borne tubular base graft 12 and stent 14 may be rolled in powdered PTFE resin to accomplish the desired deposition of PTFE powder thereon. Alternatively, the above-described PTFE liquid dispersion may be painted sprayed or otherwise applied to the surface of the stent 14 and/or outer surface of the tubular base graft 12 prior to subsequent application of the outer tubular layer 16.

DETDESC:

DETD(55)

Thereafter, as shown in FIG. 4d, the tape 17 is initially helically wrapped in overlapping fashion, on the outer surface of the stent 14,

in a first direction. In the preferred embodiment, tape of 1/2 inch width is used. The tape is helically wrapped about the stent at a pitch angle whereby 6 to 8 revolutions of the tape are applied per linear inch of the stent 14.

DETDESC:

DETD(56)

Thereafter, as shown in FIG. 4e, a second tape wrap in the opposite direction is accomplished, preferably using the same width of tape at the same pitch angle, thereby applying another 6-8 revolutions of tape 17 per linear inch of stent 14. In this manner, both wrappings of the tape 17 (FIGS. 4d and 4e) combine to form a tubular, outer PTFE layer 16 which preferably has a thickness of less than 0.1 inches, and which may be formed of 1 to 10 consecutive (e.g., laminated) layers of the tape 17. For example, when using ePTFE tape of less than 1.6 g/cc density and 1/2 inch width, the first helical wrap (FIG. 4d) may deposit four consecutive layers of tape 17 and the second helical wrap (FIG. 4e) may deposit an additional 4 layers of tape 17, thereby resulting in an outer tubular layer 16 which is made up of a total of 8 layers of such tape 17.

DETDESC:

DETD(57)

Optionally, to further promote bonding of the outer tubular layer 16 to the stent 14 and/or inner base graft 12, liquid PTFE dispersion may be sprayed, painted or otherwise applied to and dried upon the tape 17 prior to wrapping, or such liquid PTFE dispersion may be deposited by any suitable means (spraying, painting, etc.) between the outer tubular layer 16 formed by the helically wrapped tape 17 and the inner base graft 12. Or such liquid PTFE dispersion may be sprayed onto or otherwise applied to the outer surface of the helically wrapped tape 17 such the small particles of PTFE contained within the liquid dispersion will migrate inwardly through pores in the layers of tape 17, and will thereby become deposited between the outer tubular layer 16 and the inner base graft 12 prior to subsequent heating of the assembly, as described herebelow. Another alternative (and optional) method for depositing polymer (e.g., PTFE) particles between the base graft 12 and outer tubular layer 16 is by rolling the mandrel 50, having the base graft 12 and stent 14 disposed thereon, in dry, powdered polymer resin (e.g., the above-described PTFE resin) to cause such dry polymer resin to become deposited on the outer surface of the base graft 12 and/or stent 14 prior to application of the tape 17 as shown in FIGS. 4d and 4e.

DETDESC:

DETD(58)

Thereafter, as shown in FIG. 4f, ligatures 52 of stainless steel wire are tied about the opposite ends of the graft 10 so as to securely hold the base graft 12, PTFE-coated stent 14 and outer layer 16 on the mandrel 50. The mandrel, having the graft 10 disposed thereon is then heated to a temperature of 363.degree..+-.2.degree. C. for thirty minutes. Such heating will cause the outer PTFE layer 16 to heat fuse to the inner base graft 12 through the openings 19 which exist in the stent 14, and will further facilitate bonding or fusing of the PTFE coating 20 of the stent 14 to the adjacent base graft 12 and outer tape layer 16. In this manner, the desired integrally-stented PTFE tubular graft 10 is formed.

DETDESC:

DETD(59)

The . . . illustrated schematically in FIG. 4f may be carried out by any suitable means. For example, the mandrel 50 having the graft 10 and ligatures 52 disposed thereon may be placed in an oven preheated to the desired temperature, for the desired period of time. Alternatively, the mandrel, having the graft 10 and ligatures 52 disposed thereon may be rolled on a hot plate or heated surface to accomplish the desired heat fusing or bonding of the outer layer 16, base graft 12 and PTFE coating 20 of the stent 14.

DETDESC:

DETD(61)

After the U-shaped block 54 has been heated to the desired temperature, the mandrel 50, having the graft 10 and ligatures 52 disposed thereon, is inserted into the U-shaped inner region of the block 54, and is rotated, therein so as to accomplish the desired heat fusing of the tubular base graft 12, outer tape layer 16 and PTFE coating 20 of the stent 14.

DETDESC:

DETD(62)

In many applications, it will be desirable to post-flex and re-expand the stented graft 10 to ensure that the stented graft 10 is capable of undergoing full radial compression and full radial expansion, over it's complete range of intended diameters.

DETDESC:

DETD(63)

To accomplish this post-flexing and re-expansion of the stented graft 10, the stented graft 10 is removed from the mandrel 50 and is held in a heated environment, such as in the inner space of the U-shaped heater device shown in FIG. 6. Thereafter, the opposite ends of the stent 14 are pulled longitudinally away from each other to thereby radially contract the stented graft 10 to it's minimal radially compressed diameter D.sub.1. Thereafter, the stented graft 10 is allowed to self-expand. If this self-expansion of the stented graft 10 does not result in return of the stented graft 10 to its fully radially expanded diameter D.sub.2, the stented graft 10 may then be re-advanced onto the mandrel 50 to thereby force the stented graft 10 to reassume it's full radially expanded configuration of diameter D.sub.2.

DETDESC:

DETD(64)

Thereafter, when the graft is again removed from the mandrel 50, the stented graft 10 will be rendered capable of being radially compressed to it's fully compressed diameter D.sub.1, and subsequently self-expanded to it's. . .

DETDESC:

DETD(65)
F. Assembly and Construction of Internally Stented PTFE Tube Graft

DETDESC:

DETD(66)

In a first alternative embodiment of the invention, the inner base graft 12 may be eliminated or excluded, thereby providing a modified version of the stented graft 10 comprising only the stent 14 and outer tubular layer 16.

DETDESC:

DETD(67)

In this first alternative embodiment, the above-described manufacturing method is performed as described without the tubular base graft 12, thereby forming a modified version of the stented graft 10 wherein the outer tubular layer 16 of PTFE is fused only to the stent 14.

DETDESC:

DETD(68)

In embodiments wherein the stent 14 is coated with a polymer coating such as PTFE, the presence of such coating on the stent 14 will provide lubricity and biocompatability, which may render such internally stented graft suitable for use in applications wherein the exposed stent 14 will come in direct contact with biological fluid or blood flowing through the graft, thereby avoiding the need for use of the internal base graft 12.

DETDESC:

DETD(69)

Thus, . . . the present invention includes all possible embodiments wherein only the outer tubular layer 16 is utilized in conjunction with the stent 14, to provide an internally stented graft 10 which is devoid of any internal tubular base graft 12.

DETDESC:

DETD(70)
G. Assembly and Construction of Externally Stented PTFE Tube Graft

DETDESC:

DETD(71)

In . . . of the invention, the outer tubular layer 16 may be excluded or eliminated, thereby providing an externally stented PTFE tube graft which comprises only the stent 14 and the inner-base tube 12.

DETDESC:

DETD(72)

In . . . as described without the outer tubular layer 16. This results in the formation of a modified version of the stented graft 10, comprising only the inner base graft 12 and the stent 14.

DETDESC:

DETD(73)

In embodiments wherein the stent 14 is coated with a polymer coating, such as PTFE, the presence of such coating on the stent 14 will provide for enhanced biocompatability, which may render such externally stented graft suitable for implantation in blood vessels or other tubular anatomical passageways wherein the exposed exterior of the coated stent 14 comes in direct contact with vascular tissue or other tissue of the body, thereby avoiding the need for use. . .

DETDESC:

DETD(74)

Thus, this second alternative embodiment of the present invention includes all possible embodiments wherein only the inner base graft 12 is utilized in conjunction with the stent 14, to provide an externally stented graft 10 which is devoid of any outer tubular layer 16.

CLAIMS:

CLMS(1)

What is claimed is:

1. A tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:
a) a stent comprising:
i) at least one member formed in a generally cylindrical shape having an outer surface and a hollow bore which extends longitudinally therethrough to define an inner surface;
ii) said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,
iii) a plurality of lateral openings existing in said stent when said stent is at its radially expanded second diameter;
b) a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:
i) a tubular inner base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the hollow bore of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,
ii) a tubular outer layer formed of expanded, sintered PTFE tape which has a width of less than about 1 inch, said tape having been wound about the outer surface of said stent to create said tubular outer layer thereon, such that said stent is captured between said outer layer and said tubular base graft;
said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said. . .

CLAIMS:

CLMS(2)

2. The stented graft of claim 1 wherein said PTFE tape has a thickness of less than 0.015 inch and wherein said tape has been wound about said stent in overlapping fashion, such that said tubular outer layer comprises 1 to 10 layers of said tape.

CLAIMS:

CLMS(3)

3. The stented graft of claim 1 wherein said tape is helically wrapped about said stent.

CLAIMS:

CLMS(4)

4. The stented graft of claim 3 wherein said tape has a width of 1/2 inch, and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch of the stented graft.

CLAIMS:

CLMS(5)

5. The stented graft of claim 4 wherein said helical wrapping of said tape is applied twice, first in one direction and then in the opposite direction.

CLAIMS:

CLMS(6)

6. The stented graft of claim 5 wherein said helical wrappings of said tape form an outer tubular layer which is made up of 8 consecutive layers of said tape.

CLAIMS:

CLMS(7)

7. The stented graft of claim 1 wherein said stent is a self-expanding stent.

CLAIMS:

CLMS(8)

8. The stented graft of claim 7 wherein said self-expanding stent comprises a shape memory alloy which alternately exists in first and second crystalline states, and wherein the stent will assume it's radially expanded configuration when said shape memory alloy is in it's first crystalline state, and will assume. . .

CLAIMS:

CLMS(9)

9. The stented graft of claim 1 wherein said stent is a pressure-expandable stent.

CLAIMS:

CLMS(10)

10. The stented graft of claim 1 wherein said self-expanding stent is formed of a multiplicity of wire members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent wire members.

CLAIMS:

CLMS(11)

11. The stented graft of claim 10 wherein said wire members are formed of a metal alloy wherein the alloying residue is iron and. . .

CLAIMS:

CLMS(12)

12. The stented graft of claim 10 wherein some of the wire members of said stent are helically wound about a longitudinal axis in a first direction, and others of said wire members are helically wound. . . of the wire members which had been wound in the first helical direction, thereby forming a helically braided, cylindrical, wire stent.

CLAIMS:

CLMS(13)

13. The stented graft of claim 1 wherein said stent is formed of a multiplicity of plastic members which are braided into said generally cylindrical shape, and wherein said lateral openings in the stent are formed by gaps which exist between adjacent plastic members.

CLAIMS:

CLMS(14)

14. The stented graft of claim 13 wherein said plastic members are formed of a plastic selected from the group consisting of:
polytetrafluoroethylene;
fluorinated ethylene. . .

CLAIMS:

CLMS(15)

15. The stented graft of claim 1 wherein said tubular base graft comprises expanded, sintered PTFE of less than 0.10 inch thickness.

CLAIMS:

CLMS(16)

16. The stented graft of claim 1 wherein said tubular base graft comprises expanded, sintered PTFE having a density of less than 1.6 g/cc.

CLAIMS:

CLMS(17)

17. The stented graft of claim 1 wherein tubular base graft comprises expanded, sintered PTFE having a thickness of less than 0.10 inches and a density of less than 1.6 g/cc.

CLAIMS:

CLMS(18)

18. The stented graft of claim 1 wherein said tubular outer layer has a thickness of less than 0.1 inch.

CLAIMS:

CLMS(19)

19. The stented graft of claim 18 wherein said PTFE tape has a thickness of less than 0.015 inches, said tape being wrapped about said stent in overlapping fashion so as to form said tubular outer layer.

CLAIMS:

CLMS(20)

20. The stented graft of claim 1 wherein said PTFE tape has a density of less than 1.6 g/cc.

CLAIMS:

CLMS(21)

21. The stented graft of claim 1 wherein said tubular outer layer has a thickness of less than 0.1 inch and the PTFE tape has a density of less than 1.6 g/cc.

CLAIMS:

CLMS(22)

22. The stented graft of claim 1 wherein said stent further comprises:
iv) a polymer coating formed on said stent.

CLAIMS:

CLMS(23)

23. The stented graft of claim 22 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of:
polytetrafluoroethylene;
fluorinated ethylene propylene;
polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer;

polyvinyl chloride;
polypropylene;
polyethylene terephthalate;
polyvinylidene fluoride;. . .

CLAIMS:

CLMS(24)

24. The stented graft of claim 22 wherein said polymer coating was applied to said stent by the steps of:
immersing the stent in a liquid polymer dispersion;
removing the stent from the liquid polymer dispersion;
drying that liquid polymer dispersion which has remained on the stent, thereby forming said polymer coating thereon.

CLAIMS:

CLMS(25)

25. The stented graft of claim 22 wherein said polymer coating was formed on the stent by electron beam deposition.

CLAIMS:

CLMS(26)

26. The stented graft of claim 22 wherein said stent is formed of a plurality of elongate members, and wherein said polymer coating was formed on said elongate members by. . .

CLAIMS:

CLMS(27)

27. The stented graft of claim 22 wherein said base graft and said tubular outer layer are adherent to the polymer coating which is formed on said stent.

CLAIMS:

CLMS(28)

28. The stented graft of claim 1 wherein said graft further comprises:
iv) polymer particles deposited between said inner base graft and said outer tubular layer and subsequently melted to promote attachment of said tubular base graft to said tubular outer layer.

CLAIMS:

CLMS(29)

29. The stented graft of claim 28 wherein said polymer particles are PTFE.

CLAIMS:

CLMS(30)

30. The stented graft of claim 28 wherein said polymer particles are melted by heat.

CLAIMS:

CLMS(31)

31. The stented graft of claim 29 wherein said polymer particles are melted by solvent.

CLAIMS:

CLMS(32)

32. The stented graft of claim 28 wherein said polymer particles are deposited by applying a liquid polymer particle dispersion to one of said base graft and said tubular outer layer, prior to assembly thereof.

CLAIMS:

CLMS(33)

33. The stented graft of claim 28 wherein said polymer particles are deposited between said tubular base graft and said tubular outer layer by applying a liquid dispersion of polymer particles to the exterior of said tubular outer. . .

CLAIMS:

CLMS(34)

34. A tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:
a) a stent comprising:
i) at least one member formed in a generally cylindrical shape having an outer surface and a hollow bore which extends longitudinally therethrough to define an inner surface;
ii) said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,
iii) a plurality of lateral openings existing in said stent when said stent is at its radially expanded second diameter;
b) a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:
i) a tubular inner base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the hollow bore of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,
ii) a tubular outer layer formed of expanded, sintered PTFE tape which has a thickness of less than 0.015 inches, said tape being wrapped about the outer surface of said stent in overlapping fashion so as to form said tubular outer layer, such that said stent is captured between said outer layer and said tubular base graft;
c) said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said. . .

CLAIMS:

CLMS(35)

35. A tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:
a) a stent comprising:
i) at least one member formed in a generally cylindrical shape having an outer surface and a hollow bore which extends longitudinally therethrough to define an inner surface;
ii) said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,
iii) a plurality of lateral openings existing in said stent when said stent is at its radially expanded second diameter;
b) a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:
i) a tubular inner base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the hollow bore of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,
ii) a tubular outer layer formed of expanded, sintered PTFE, said outer layer being disposed about the outer surface of said stent such that said stent is captured between said outer layer and said tubular base graft; and,
c) polymer particles deposited between said inner base graft and said outer tubular later and subsequently melted to promote attachment of said tubular base graft to said tubular outer layer;
said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said. . .

CLAIMS:

CLMS(36)

36. The stented graft of claim 35 wherein said polymer particles are PTFE.

CLAIMS:

CLMS(37)

37. The stented graft of claim 35 wherein said polymer particles are melted by heat.

CLAIMS:

CLMS(38)

38. The stented graft of claim 35 wherein said polymer particles are melted by solvent.

CLAIMS:

CLMS(39)

39. The stented graft of claim 35 wherein said polymer particles are deposited by applying a liquid polymer particle dispersion to one of said base graft and said tubular outer layer, prior to assembly thereof.

CLAIMS:

CLMS(40)

40. The stented graft of claim 35 wherein said polymer particles are deposited between said tubular base graft and said tubular outer layer by applying a liquid dispersion of polymer particles to the exterior of said tubular outer. . .

CLAIMS:

CLMS(41)

41. A tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:
a) a stent formed in a generally cylindrical shape having an outer surface and a hollow bore which extends longitudinally therethrough to define an inner surface, the stent having an initially radially collapsed state with a diameter which is substantially equal to said first diameter, and a radially. . . diameter which is substantially equal to said second diameter, and wherein a plurality of lateral openings are formed in said stent in its radially expanded state;
b) a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:
i) a tubular inner base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the hollow bore of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,
ii) a tubular outer layer formed of expanded, sintered PTFE, said outer layer being disposed about the outer surface of said stent such that said stent is captured between said outer layer and said tubular base graft; and,
c) PTFE particles deposited between said inner base graft and said outer tubular later and subsequently melted to promote attachment of said tubular base graft to said tubular outer layer;
said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said. . .

CLAIMS:

CLMS(42)

42. The stented graft of claim 41 wherein said PTFE particles are melted by heat.

CLAIMS:

CLMS(43)

43. The stented graft of claim 41 wherein said PTFE particles are melted by solvent.

CLAIMS:

CLMS(44)

44. The stented graft of claim 41 wherein said PTFE particles are deposited by applying a liquid polymer particle dispersion to one of said base graft and said tubular outer layer, prior to assembly thereof.

CLAIMS:

CLMS(45)

45. The stented graft of claim 41 wherein said PTFE particles are deposited between said tubular base graft and said tubular outer layer by applying a liquid dispersion of polymer particles to the exterior of said tubular outer. . .

US PAT NO: 5,925,075 [IMAGE AVAILABLE] L1: 2 of 37
TITLE: Intraluminal stent graft

ABSTRACT:
A tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene which is less than 0.10 mm thick. The covering may be on the exterior surface of the stent, or on the interior surface of the stent, or both. The covering may be affixed to the stent by an adhesive which is preferably fluorinated ethylene propylene.

SUMMARY:

BSUM(5)

Alternative methods have evolved which use intraluminal vascular grafts in the form of adjustable stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by. . .

SUMMARY:

BSUM(6)

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

SUMMARY:

BSUM(8)

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at. . . location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of adjustable stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

SUMMARY:

BSUM(9)

Intraluminal . . . No. 3,657,744 to Ersek describes a method of using one or more adjustable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

SUMMARY:

BSUM(10)

Choudhury, U.S. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terephthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

SUMMARY:

BSUM(11)

Rhodes, . . . sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX.RTM. Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff, Ariz.) or Impra.RTM. Graft (Impra, Inc. Tempe, Ariz.). Both the GORE-TEX Vascular

Graft and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra graft as the sleeve component is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the. . . insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of manufacturing an extruded, longitudinally expanded. . .

SUMMARY:

BSUM(13)

The present invention is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular covering of porous expanded PTFE film affixed to the stent, said covering being less than about 0.10 mm thick.

SUMMARY:

BSUM(14)

Porous . . . type as taught by U.S. Pat. No. 4,776,337 which typically require a balloon catheter to increase the diameter of the stent within a blood vessel. The term self-expanding refers to stents which increase in diameter by various other means. Stents of. . .

SUMMARY:

BSUM(15)

The . . . covering of porous expanded PTFE film may be affixed to either the exterior surface or the luminal surface of the stent. Alternatively, a first tubular covering of porous expanded PTFE film may be affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded PTFE film may be affixed to the luminal surface of the tubular diametrically adjustable stent. The first and second tubular coverings of porous expanded PTFE film may be affixed to each other through the openings through the wall of the stent.

SUMMARY:

BSUM(16)

The porous expanded PTFE film may be affixed to the stent with an adhesive. The adhesive may be a thermoplastic adhesive and more preferably a thermoplastic fluoropolymer adhesive such as fluorinated. . . and second tubular coverings of expanded PTFE film are affixed to each other through the multiplicity of openings in the stent wall, the two coverings may be affixed by heating them above the crystalline melt point of the PTFE film adequately to cause them to thermally adhere, or alternatively they may be affixed by an adhesive such as FEP.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent.

DRAWING DESC:

DRWD(5)

FIG. 4 is a transverse cross section of the stent of Example 1 having a luminal layer of porous expanded PTFE film with longitudinally-oriented fibrils and an exterior layer of. . .

DRAWING DESC:

DRWD(6)

FIG. 5 is a transverse cross section of the stent of Example 2 having a luminal layer of porous expanded PTFE film with biaxially-oriented fibrils.

DRAWING DESC:

DRWD(7)

FIG. 6 is a transverse cross section of the stent of Example 3 having an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

DRAWING DESC:

DRWD(8)

FIG. 7 describes a method of collapsing a previously outwardly adjusted balloon-expandable stent.

DRAWING DESC:

DRWD(9)

FIG. 8 describes the fitting of a single tubular sleeve to both the exterior and luminal surfaces of a stent.

DRAWING DESC:

DRWD(10)

FIG. 9 describes the removal a covered, braided wire stent of the self-expanding type from a manufacturing mandrel by everting the braided wire, thereby placing the covering on the luminal surface of the stent.

DETDESC:

DETD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. While the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be. . .

DETDESC:

DETD(3)

The stent may be provided with an exterior covering of porous expanded PTFE film, or a luminal covering of porous expanded PTFE. . .

DETDESC:

DETD(6)

Wall thickness measurements of intraluminal graft stent coverings were determined by cutting away a portion of the covering that covered an opening through the stent wall. The thickness of the sample portion was measured by placing the sample portion between the pads of a Mitutoyo. . .

DETDESC:

DETD(7)

The following examples of intraluminal stent grafts are intended to be illustrative only and are not intended to limit the scope of the invention to only. . .

DETDESC:

DETD(9)

A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film. This 3 cm long stent was formed from 0.25 mm diameter Nitinol wire into a tubular shape of interlocking hexagons. The luminal and exterior coverings. . . to each other. The luminal covering was provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering was provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the luminal and exterior coverings was a porous expanded PTFE film having a discontinuous, porous. . .

DETDESC:

DETD(17)

A . . . axis of the mandrel; the FEP-coated side of the film faced away from the surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The 3 cm length of the stent was centered over the 3.0 cm length of film-wrapped mandrel. The stent was then provided with an exterior covering 47 of a 3.0 cm wide tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so

that the edges of the circumferentially-wrapped tape overlapped by about 3 mm to form seam 49. The circumferentially wrapped covering was oriented so that the FEP-coated side of the tape faced inward in contact with the exterior surface of the stent and the outward facing FEP-coated surface of the luminal layer of film exposed through the openings in the stent. Except for the overlapped seam edges 49, the circumferentially-wrapped covering was only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape were circumferentially-oriented about the exterior stent surface.

DETDESC:

DETD(18)

The . . . from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the film-wrapped stent. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the luminal layer of film was adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the stent. The combined thickness of the luminal and exterior coverings was about 0.025 mm.

DETDESC:

DETD(19)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(21)

A Nitinol wire stent of the same type used for Example 1 was provided with a luminal covering of a porous expanded PTFE film. . . had a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The mandrel assembly was then placed into an oven set. . . at 360.degree. C. for four minutes. After removal from the oven and subsequent cooling, the mandrel was removed from the stent leaving the wrapped film adhered to the luminal surface of the stent. This film was then peeled from the luminal stent surface, leaving the FEP-coating and some small shreds of residual porous expanded PTFE adhered to the luminal surface of the stent wires. By removing the film and leaving the FEP adhesive on the luminal stent surface, the film served only as a release substrate for the application of the adhesive to the stent surface.

DETDESC:

DETD(23)

The . . . contacted with the surface of a hand-held iron set at 400.degree. C. to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam was trimmed away and discarded. The stent was again carefully fitted over the film-covered mandrel. The resulting assembly was placed into an oven set at 380.degree. C. for three minutes and then removed and allowed to cool, after which the mandrel was removed from the stent. The porous expanded PTFE film appeared to be well adhered to the luminal surface of the wire stent by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film. . .

DETDESC:

DETD(24)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(26)

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) was adjusted from its collapsed. . . 8.0 mm by inserting a tapered stainless steel mandrel followed by a straight 8.0 mm diameter stainless steel mandrel. This stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. This was accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the stent. This exterior covering 61 is described by the transverse cross section of FIG. 6. A 2 mm wide seam 45. . . over these edges and applying heat from a hand-held iron with a surface temperature of about 400.degree. C. The film-wrapped stent 65 was then placed into an oven set at 380.degree. C. for 3 minutes, after which it was removed and allowed to cool. The film appeared to be well adhered to the exterior surface of the stent. The wall thickness of the film covering was about 0.01 mm. The enlarged stent was then collapsed by the following process.

DETDESC:

DETD(27)

A series of 20 cm long 6-0 sutures were tied individually to each of the closed metal stent openings adjacent to one end of a stent. The film-covered stent was provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping was intended as a dry lubricant. As described by FIG. 7 which omits the exterior film covering for clarity, the enlarged stent 71 was then pulled by these sutures 77 through a tapered die 75 of round cross section and 2.5 cm. . . bore at its entrance 78 and a 4.5 mm diameter bore at its exit 79. The result was that the stent was collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous expanded PTFE film aided in making it possible to pull the stent through the die. This temporary covering was removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an appropriately sized, smaller diameter exit bore would result in collapsing the stent to its original collapsed diameter. The film-covered stent was again enlarged to a diameter of 8 mm using a balloon catheter followed by a tapered stainless steel mandrel.. . . The covering of porous expanded PTFE film appeared to be fully intact after the collapsing and enlarging of the film-covered stent.

DETDESC:

DETD(28)

Stent coverings may be affixed to a stent surface by variations on this method. For example, a tubular sleeve may be made from a film of porous expanded PTFE and inverted back into itself and fitted over the inner and outer surfaces of a stent as shown by FIG. 8. The inner 83 and outer 85 portions of the tubular sleeve 81 may be thermally adhered to each other through the openings in the stent wall, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends 87 of the tube together.

DETDESC:

DETD(30)

A . . . single layer, approximate 1 mm overlap covering of porous expanded PTFE film by helically wrapping the wire with a narrow tape cut from a sheet of porous expanded PTFE film. The tape used was 6 mm wide, 0.01 mm thick, 0.3 g/cc density, and had uniaxially-oriented fibrils of about 50 micron fibril length. This tape-covered wire was then heated by pulling the wire through the 0.14 mm diameter orifice of a 2.5 cm long die heated to 400.degree. C., at a rate of 1.5 meters per minute, thereby adhering the overlapped edges of the tape together and thereby adhering the tape to the wire. This wire was then cut into shorter lengths and spooled onto 16 bobbins. These bobbins were used. . .

DETDESC:

DETD(31)

A . . . a braided covering of the above wire was applied at a density of about 16 picks/cm. An additional covering of tape cut from a sheet of porous expanded PTFE film was then helically wrapped over the surface of the wire-braided PTFE mandrel. The tape used for this helical wrapping was of 0.01 mm thickness, 0.3 g/cc density, about 50 micron fibril length and 12. . . C. for four minutes, after which it was

removed and allowed to cool. As shown by FIG. 9, the wire-braided stent 91 with the exterior covering of porous expanded PTFE tape was then removed from the non-porous PTFE mandrel 93 by folding the ends 95 of the braided wires back on. . . the braided assembly from the mandrel resulted in the helical wrapping of film being located on the lumen of the stent. This construction offered good self-expanding characteristics in that when longitudinal tension was placed on the stent, the length of the stent increased and the diameter decreased. Upon release of tension, the stent immediately recovered its previous shorter length and larger diameter. This film-covered stent is therefore expected to be useful as a self-expanding stent.

CLAIMS:

CLMS(1)

We claim:

1. A tubular intraluminal graft comprising a length of wire having a surface, said wire having a covering of porous expanded polytetrafluoroethylene about the surface of the wire to create a covered wire, said covered wire being formed into a tubular stent.

CLAIMS:

CLMS(2)

2. A graft according to claim 1 wherein said stent is provided with a covering of porous expanded polytetrafluoroethylene.

CLAIMS:

CLMS(3)

3. A graft according to claim 2 wherein said covering is provided on a luminal surface of the stent.

CLAIMS:

CLMS(4)

4. A graft according to claim 2 wherein said covering is provided on an exterior surface of the stent.

CLAIMS:

CLMS(5)

5. A graft according to claim 1 wherein said tubular stent is a self-expanding stent.

CLAIMS:

CLMS(6)

6. A graft according to claim 5 wherein said stent is provided with a covering of porous expanded polytetrafluoroethylene.

CLAIMS:

CLMS(7)

7. A graft according to claim 6 wherein said covering is provided on a luminal surface of the stent.

CLAIMS:

CLMS(8)

8. A graft according to claim 6 wherein said covering is provided on an exterior surface of the stent.

US PAT NO: 5,855,598 [IMAGE AVAILABLE] L1: 3 of 37

ABSTRACT:
An endoluminal graft which is both expandable and supportive is provided in a form suitable for use in a branched body vessel location. The graft expands between a first diameter and a second, larger diameter. The support component is an expandable stent endoprosthesis. A liner is applied to the endoprosthesis in the form of a compliant wall material that is porous and biocompatible in order to allow normal cellular invasion upon implantation, without stenosis, when the expandable and supportive graft is at its second diameter. The supportive endoluminal graft is preferably provided as a plurality of components that are deployed separately at the branching body vessel location, one of. . .

SUMMARY:

BSUM(2)

This . . . relates to supportive endoluminal grafts which have the ability to be delivered transluminally and expanded in place to provide a graft that is endoluminally positioned and placed, with the aid of an appropriate inserter or catheter, and that remains so placed in order to both repair a vessel defect and provide lasting support at the location of the graft. In its broadest sense, the graft preferably combines into a single structure both an expandable luminal prosthesis tubular support component and a compliant graft component secured thereto. The expandable supportive endoluminal graft takes on a bifurcated or branched structure made up of components that are designed to be positioned in a bifurcated. . . to each other, preferably during deployment or repair and support of vessel locations at or near branching sites. Preferably, the graft component is compliant, stretchable or elastomeric and does not substantially inhibit expansion of the tubular support component while simultaneously exhibiting. . .

SUMMARY:

BSUM(4)

Also known are stent devices, which are placed or implanted within a blood vessel or other body cavity or vessel for treating occlusions, stenoses,. . .

SUMMARY:

BSUM(5)

One common procedure for implanting a stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the diseased portion of the vessel. Various constructions and designs of stents are known. U.S. Pat. No. 4,140,126 describes a technique for positioning an elongated cylindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall, the stent being a cylinder that expands to an implanted configuration after insertion with the aid of a catheter. Other such devices. . . spring to expand. Spring-into-place stents are shown in U.S. Pat. No. 4,580,568. U.S. Pat. No. 4,733,665 shows a number of stent configurations for implantation with the aid of a balloon catheter. U.S. Pat. No. 5,019,090 shows a generally cylindrical stent formed from a wire that is bent into a series of tight turns and then spirally wound about a cylindrical mandrel to form the stent. When radially outwardly directed forces are applied to the stent, such as by the balloon of an angioplasty catheter, the sharp bends open up and the stent diameter enlarges. U.S. Pat. No. 4,994,071 describes a bifurcating stent having a plurality of wire loops that are interconnected by an elongated wire backbone and/or by wire connections and half. . .

SUMMARY:

BSUM(6)

Stents themselves often do not encourage normal cellular invasion and can lead to undisciplined development of cells in the stent mesh, with rapid development of cellular hyperplasia. Grafts alone do not provide adequate support in certain instances. Copending application of Jean-Pierre Dereume, Ser. No. 08/546,524, entitled "Luminal Graft Endoprostheses and Manufacture Thereof" describes grafts that have the ability to carry out dilatation and/or support functions. An expandable tubular support component and an elastomeric graft component are combined into a single device wherein the graft material is secured to either or both of the internal and external surfaces of the expandable support component. The graft material is produced by a spinning technique such as that described in U.S. Pat. No. 4,475,972. Also, luminal endoprostheses with. . . Aneurysm", Journal of Surgical Research, 40, 305-309, 1986, and U.S. Pat. Nos. 5,019,090 and 5,092,877 mention the possibility to coat stent materials with porous or textured surfaces for cellular ingrowth or with non-thrombogenic agents and/or drugs. The various patents and publications. . .

SUMMARY:

BSUM(7)

By . . . to a second diameter which is greater than the first. When it is at its first diameter, the expandable supportive graft is of a size and shape suitable for insertion into the desired body passageway. The material of the graft is substantially inert and preferably has a generally cylindrical cover and/or lining generally over the outside and/or inside surface of. . . about 2 to 4 times or more of its unexpanded diameter. Components of the branched or bifurcated expandable

supportive endoluminal graft preferably are deployable separately such that each component is properly positioned with respect to the other into the desired branched. . .

SUMMARY:

BSUM(8)

It is a general object of the present invention to provide an improved branched endoluminal graft that is expandable in place and, once expanded, is self-supporting.

SUMMARY:

BSUM(10)

Another object of the present invention is to provide an improved expandable reinforced graft that is delivered by way of introducers, balloon catheters or similar devices, and which facilitates good tissue ingrowth.

SUMMARY:

BSUM(11)

Another object of this invention is to provide an improved endoluminal graft which fully covers diseased or damaged areas for carrying out luminal repairs or treatments, such as repair of aneurysms.

SUMMARY:

BSUM(12)

Another object of the present invention is to provide an improved endoluminal graft wherein the endoprosthesis is substantially enclosed within biocompatible compliant material which is presented to the surrounding tissue and blood or. . .

SUMMARY:

BSUM(13)

Another object of this invention is to provide an expandable, supportive graft that can be tailored to meet a variety of needs, including a single graft designed to address more than a single objective.

SUMMARY:

BSUM(14)

Another object of the present invention is to provide a self-expanding reinforced graft device that is delivered in its elongated and compressed state from within a tubular member and deployed by moving same. . .

SUMMARY:

BSUM(16)

A further object of the present invention is to provide a component branched endoluminal graft having a longitudinally creased trunk component and at least one cylindrical branch component, which components are expanded separately after endoluminal delivery and which form a bifurcated graft once positioned with respect to each other and expanded.

SUMMARY:

BSUM(17)

Another object of this invention is to provide an improved method of forming a branched endoluminal graft incorporating a longitudinal creasing procedure.

SUMMARY:

BSUM(18)

Another object of the present invention is to provide an improved method of assembling a branched endoluminal graft.

DRAWING DESC:

DRWD(3)

FIG. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction in accordance with the

invention;

DRAWING DESC:

DRWD(5)

FIG. 3 is a perspective view, partially cut away, of another embodiment of the expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(7)

FIG. 5 is a perspective view, partially cut away, of a further embodiment of the expandable luminal graft construction;

DRAWING DESC:

DRWD(9)

FIG. 7 is a perspective view, partially cut away, of a bifurcated expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(13)

FIG. 13 shows this bifurcated supportive graft after completion of the expansion procedure;

DRAWING DESC:

DRWD(14)

FIG. 14 illustrates another embodiment of a bifurcated expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(15)

FIGS. 15, 16 and 17 illustrate implantation and assembly of the graft of FIG. 14;

DRAWING DESC:

DRWD(16)

FIGS. 18, 19, 20 and 21 illustrate a component branched graft and various stages of its separate, component deployment within a body vessel to repair an aneurysm, FIGS. 18 and 19. . .

DETDESC:

DETD(2)

An embodiment of expandable supportive luminal graft construction is generally illustrated in FIG. 1 at 21. This embodiment includes a braided tubular support component having generally helically. . .

DETDESC:

DETD(4)

Liner . . . shown in FIGS. 18 and 20) is used to prevent automatic radial expansion prior to deployment. When the expandable supportive graft 21 is to include a cover 23, the mandrel is again rotated, and the electrostatic spinning is again accomplished in. . . sponge such that the still tacky outer fibers bond to the inner fibers thereby encapsulating the tubular support within the graft.

DETDESC:

DETD(6)

It . . . both are present, is made of an elastomeric material which retains its compliant properties after construction of the expandable supportive graft 21 is completed. In this regard, the graft itself is also elastomeric and compliant. Accordingly, the graft 21 is delivered transluminally, such as by being pulled down onto the balloon of a catheter or into an inserter tube and then percutaneously inserted and positioned to the location where the repair is needed. For a non-spring loaded graft, the balloon is then inflated to longitudinally shorten and radially expand the graft 21 into engagement with the vessel walls. Because of the compliance of the cover 23 and/or liner 24, and because of the hoop strength of the braided tubular support 22, the graft 21 will remain in place. In the

illustrated embodiment, ends 25 of the tubular support are exposed and are not. . . 25 to directly engage the vessel wall, if desired in the particular application, in order to assist in anchoring the graft 21 in place. Liner 24 also can be sized so as to not cover the exposed ends 25, or it. . .

DETDESC:

DETD(7)

Alternatively, when a braided tubular support such as that illustrated in FIGS. 1 and 2 is incorporated into the graft according to the present invention in a non-spring-loaded form, transluminal delivery can be made by way of a catheter or. . . other in order to thereby longitudinally compress the endoprosthesis. Delivery tools for spring-loaded grafts include a sleeve that maintains the graft at its compressed diameter until the graft is positioned for deployment such as from the end of an insertion catheter to its auto-expanded state.

DETDESC:

DETD(8)

With reference to the embodiment illustrated in FIGS. 3 and 4, an expandable supportive graft is illustrated at 31. The illustrated tubular support component 32 is constructed of sinusoidally configured wire helically wound into a. . . as a percent by volume of a pre-elution mixture thereof with the polymer of the cover or liner. When a graft 31 having both a cover 33 and a liner 34 is prepared, a mandrel or rod is dipped into a. . .

DETDESC:

DETD(10)

As . . . particular repair or treatment to be carried out. With this approach, the exposed ends 35 will assist in maintaining the graft 32 in place by mechanical engagement between the exposed ends 35 and the vessel being repaired or treated and/or by. . . exposed ends to expand radially outwardly in an amount somewhat greater than that of the rest of the expandable supportive graft and into the surrounding tissue. It is also contemplated that mechanical means can be used to assist in joining the. . . Illustrated staples are shown at 36 in FIG. 3. They can be incorporated at other locations as well along the graft. One or more windows 37 can be formed through the cover and/or liner and/or tubular support in order to feed. . .

DETDESC:

DETD(11)

FIGS. 5 and 6 illustrate a further embodiment of an expandable supported graft, generally designated as 41. Shown is a mesh tubular support component, generally designated as 42, such as those of the. . .

DETDESC:

DETD(14)

FIGS. 7 and 8 illustrate an embodiment wherein the graft takes the form of a bifurcated expandable supportive graft, generally designated at 51. Included is a joined-ring bifurcated tubular support 52. Also shown are a bifurcated cover 53, a bifurcated lining 54 and exposed ends 55, 56, 57. This particular bifurcating graft is well-suited for insertion into a branching vessel.

DETDESC:

DETD(17)

With . . . the cover and/or liner. In an especially advantageous arrangement when using these fiber spinning techniques in forming an expandable supportive graft in accordance with the general aspects of this invention which has both a liner and a cover, the cover is. . .

DETDESC:

DETD(18)

With . . . bifurcating vessel, each of them into different legs 66, 67 of the bifurcating vessel. Thereafter, the unexpanded bifurcated expandable supportive graft 51 is slipped over the proximal ends of the guidewires and routed to the branches of the blood vessel. The unexpanded bifurcated graft can be introduced from an arteriotomy proximal to the bifurcation such as from the brachial artery in the arm, or the unexpanded bifurcated graft can be introduced from the femoral artery in the leg, pushed proximally past the bifurcation and then pulled

back distally. . .

DETDESC:

DETD(19)

The two branches 62, 63 of the graft 51 are routed separately over the guidewires 64, 65, respectively, and guided, typically with the help of a guide catheter, into the patient until the graft is positioned as shown in FIG. 9. The graft 51 is initially fixed in place as follows. One of the guidewires 65 is removed, and a balloon catheter 68. . . and inflated to expand the trunk 61 into contact with the vessel walls. This deployment is suitable to secure the graft 51 in place at that location of the vessel.

DETDESC:

DETD(20)

The . . . is then deflated. If this balloon catheter is also suitable for use in expanding the branches 62, 63 of the graft 51, same is then inserted into an unexpanded branch 62 and radially expanded as generally shown in FIG. 11. If. . . regard, then another balloon catheter 69 effects this function. FIG. 12 shows inflation of the other branch 63 of the graft 51 in a similar manner. FIG. 13 illustrates the fully deployed and expanded bifurcated support graft 51 positioned in place within the bifurcated location. Alternatively, a bifurcated dilation balloon on a bifurcated catheter (not shown) can. . .

DETDESC:

DETD(21)

Preferably the branched and assembled expandable supportive graft is of the spring-into-place type; as such, it will be manipulated to be reduced in diameter and placed within an. . . guidewires and contained within the guiding catheter until proper placement within the bifurcating location. This type of bifurcated expandable supportive graft is deployed by being ejected into place, typically by advancing a small inner catheter through the guiding catheter into contact with the bifurcating graft in accordance with the procedure generally used for spring-into-place stents.

DETDESC:

DETD(22)

The . . . illustrated in FIGS. 9 through 13 can be characterized as prograde deployment. Retrograde deployment is also possible. The entire bifurcating graft for retrograde deployment is advanced over a single guidewire through one branch of the blood vessel past the point of bifurcation. A second guidewire is then steered down the opposite limb of the graft, and a snare is used. The snare, which is passed retrograde through the opposite vessel, is then used to pull. . . place. Partial balloon inflation in the unbranched or trunk portion of the blood vessel is then used to draw the graft down into position prior to balloon dilatation of both the trunk and branched portions of the graft. Because blood flow is prograde under these circumstances, the contact between the bifurcation of the graft and the bifurcation of the blood vessel helps to prevent the graft from migrating distally, thus reducing the need for active fixation of the graft to the blood vessel.

DETDESC:

DETD(23)

Another bifurcated endoprosthesis or expandable supportive graft is generally designated 81 in FIG. 14. Separate components are included. In this case tubular supporting component(s) are, prior to. . . trunk component. In this embodiment, a fully independent tubular supporting component 82 is located at the trunk position of the graft 81. A bifurcated stretchable wall 83 is in contact with the independent tubular supporting component 82 as either or both. . .

DETDESC:

DETD(24)

Implantation of this bifurcated expandable supportive graft is depicted in FIGS. 14, 15, 16 and 17. Dual guidewires 64, 65 can be used to properly position the unexpanded bifurcated graft 81 within the bifurcating vessel as shown in FIG. 14. A balloon catheter 68 or similarly functioning device is inserted. . . component 82 and the trunk portion 84 of the bifurcated stretchable wall 83. This deployment initially secures the bifurcated supporting graft into place at that

location of the vessel, as shown in FIG. 15. The balloon catheter is then deflated and. . .

DETDESC:

DETD(26)

A further bifurcated endoprosthesis or expandable supportive graft is one in which the separate components are each expandable supportive graft members. These separate components are illustrated in FIG. 18 through FIG. 21, which also illustrate their separate deployment with respect. . . for example of a length which terminates within the dent or crease 124. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means an introducer containing compressed expandable supportive graft components.

DETDESC:

DETD(28)

FIG. 20 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (FIG. 21) radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg. . . deployed trunk component 101. This positioning is illustrated in FIG. 21. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery. . .

DETDESC:

DETD(29)

In . . . removed, the component 115 had expanded radially and was deployed. Thus, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together as shown in FIG. 21, as well as generally. . .

DETDESC:

DETD(30)

It . . . of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs,. . .

DETDESC:

DETD(32)

Trunk component 101 includes a stent or tubular supporting component 121. Also included is a liner, generally designated as 122. A further liner 123 preferably is located interiorly of the liner 122. Liners 122, 123 are secured within the stent component 121 in order to provide proper porosity for an endoprosthesis.

DETDESC:

DETD(33)

Trunk . . . provided depending upon the degree of branching desired. It will be appreciated that one or more tubular expandable supportive leg graft components will be provided in order to slide into the branched passageways which are thus defined by the indent(s). In. . .

DETDESC:

DETD(36)

Trunk component 101c includes a stent or tubular supporting component 121c, as perhaps best seen in FIG. 32. Also included is a liner, generally designated as. . .

DETDESC:

DETD(37)

Each leg 109c, 113c is secured to the generally tubular stent component 121c at outside portions thereof, particularly at adhesion zones 124c and 125c. The remainder of the leg portions 109c and 113c are not so bonded to the stent portion 121c. This facilitates formation of the leg portions, which are typically pinched along the length of the

legs in. . .

DETDESC:

DETD(38)

In FIG. 33, means are included in the trunk component 101d which provides enhanced securement upon implantation. A stent component 129d is included which has a substantially higher pitch angle (for example, between about 140.degree. and 180.degree.) than does the stent portion 121d therebelow within which the legs are positioned (for example, at a pitch angle of between about 70.degree. and 90.degree.). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121c of the trunk component 101c. A barb 130 is also shown in order to further assist in securement of. . . the artery wall. When desired, the barb-type of structure can be a backing ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

DETDESC:

DETD(39)

Any of the various expandable supportive endoluminal graft, or stent graft, constructions discussed or referred to herein can be used in order to construct devices in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable. . . devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such. . .

DETDESC:

DETD(42)

It . . . defects or diseased areas, including at or in proximity to sites of vascular bifurcations, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the grafts interface with body components that facilitate normal cellular invasion without stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially. . .

DETDESC:

DETD(43)

In . . . of a metallic structure imparting expansion attributes. U.S. Pat. Nos. 4,994,071 and 5,360,443 describe bifurcated devices which use expandable metallic stent structures and textile materials allowing branching of fluid flow. In general, materials of these patents, incorporated by reference hereinto, can. . .

DETDESC:

DETD(44)

More specifically, the tubular supportive component preferably is a braided tubular stent body made of metal alloy or any other material that is flexible, while being rigid and resilient when thus braided.. . .

DETDESC:

DETD(45)

Concerning . . . polymeric materials in the form of a membrane or textile-like material, the objective being to reduce the porosity of the stent for proper tissue ingrowth and fluid tightness. Exemplary polymeric materials include polyesters such as polyethylene terephthalate, polyolefins such as polypropylene,. . .

DETDESC:

DETD(47)

In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more biocompatible. Included are the use of pyrolytic carbon, hydrogels and the like. The

surface treatments can also provide for. . .

DETDESC:

DETD(53)

In . . . heat processed in order to set the desired diameter and mechanical properties of the main body. Once this flexible metallic stent with conformed shape is thus prepared, it is preferably lined as discussed elsewhere herein. It will be noted that the. . .

DETDESC:

DETD(54)

The expandable supportive graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or disease. . . the anatomy of the vessel. For example, it can be desirable to have the support component of the expandable supportive graft at locations other than throughout the entirety of the graft as specifically illustrated in FIGS. 1 through 4 hereof. The bifurcated graft of FIGS. 7 and 8 shows some separation along the support component, such as between the trunk 61 and the. . . branches 62, 63. It is also possible, with the grafts in accordance with the present invention, to provide an expandable graft having its supportive property emanating from one or more support components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a support component which can be presented at one end, both ends, or spaced along the expandable supportive graft in accordance with invention.

DETDESC:

DETD(55)

Such a structure is generally illustrated in FIG. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first support component 72 and another or second support component 73. The expandable supportive graft in accordance with the present invention provides the tailorability advantage of being able to vary within a single graft the configuration, structure and properties of the support component or components of the graft. These various properties allow the expandable supportive graft to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support may. . . location being treated, while a less rigid supportive area is needed at another, generally adjoining location. By the expandable supportive graft in accordance with this invention, a single graft can be deployed in order to effect two or more different functions. By achieving multiple support and/or repair functions with. . .

DETDESC:

DETD(56)

With . . . dissection with or without intimal flaps, thrombosis, embolism, and the like. Another suitable use is for dilating and/or supporting vascular graft bifurcations and the like. Additionally, lesions affecting vascular trifurcations can be treated. Also treatable are obstructed openings characterized by exaggerated. . .

DETDESC:

DETD(58)

This example illustrates the formation of a branched expandable supportive endoluminal graft having an expanded internal diameter of 10 mm and which is bifurcated to accommodate two endoluminal supportive graft legs of 5 to 7 mm in diameter. A liner of non-woven polycarbonate urethane (Corethane.RTM.) was spun by winding over. . .

DETDESC:

DETD(60)

The two endoluminal tubular expandable supportive graft leg components are prepared in accordance with a similar procedure which is simpler because of the cylindrical shape of these. . .

DETDESC:

DETD(66)

A branched vascular expandable supportive endoluminal graft was made using a 16 mm diameter, 12 cm long Wallstent.RTM. device as the support component in the following manner.. . . an additional 3 hours at 110.degree. C., after which the assembly is removed from the mandrel. The

expandable supportive endoluminal graft formed in this manner had the bulk of the urethane mesh on the inside of the stent. The longitudinal locations which are not secured to the stent are joined together to form a seam to define two legs as generally shown in FIG. 31.

DETDESC:

DETD(68)

A branched aortic expandable supportive endoluminal graft is made in the following manner. An aortic trunk supportive endoluminal graft is fabricated using a 16 mm diameter, 12 cm long support component. First, a 16 mm mandrel is rotated on. . . for an additional 3 hours at 110.degree. C., after which the assembly is removed from the mandrel. The supportive endoluminal graft formed in this manner has fiber diameters of 10 to 20.mu. and pore sizes ranging from 10 to 60.mu..

DETDESC:

DETD(72)

A branched expandable supportive endoluminal graft is provided for deployment within and repair of aorto-iliac aneurysms. A generally tubular metallic stent of the self-expandable type is adhered to the outside of a porous spun liner as follows. The graft is wound or spun from filaments deposited onto a rotating mandrel in order to form a cylindrical graft having crossing strands generally adhered together. The resulting inner liner, after it is dried, has a stent component placed over it. Then, an area of the stent is masked, such as with a piece of tape, at the location where an internal seam is to be positioned in the trunk component of the supportive endoluminal graft. The masking can take on a shape on the order of the triangular areas illustrated in FIG. 32, with the. . . seam, and the lower apex forming the lower "crotch" of the seam. Additional fibers are then spun over the entire stent and pressed through the stent intersticies to be certain that the stent is secured to the liner. This continues until all areas of the stent are well-bonded except for the masked areas. After removal of the mandrel and of the masking material, the initially formed inner liner is free to be pinched along its length and sutured, sewed and/or glued and the like to form two distinct leg portions and a trunk portion of the liner. The resulting trunk component. . .

DETDESC:

DETD(73)

The leg components of the branched supportive endoluminal graft in accordance with this Example are individually made in a similar manner. The liner is formed by spinning compliant fibers over a rotating mandrel, a tubular stent component is positioned thereover and secured in place, and additional fibers are wound with the rotating mandrel. The stent is thus encapsulated between the liner fibers and the cover fibers, preferably with the aid of a soft roller or sponge to force the cover strands into the intersticies of the stent component and securement to the underlying liner fibers. After removal from the mandrel, the resulting tubular supported graft component, suitable for use as both the iliac components, is trimmed to proper length.

DETDESC:

DETD(75)

A branched aortic expandable supportive endoluminal graft was made using a liner of polycarbonate urethane. The cylindrical liner was flattened, and a longitudinal seam was formed by heat sealing together the flattened opposing portions along a thus formed seal line. A self-expanding cylindrical stent-like support component was coated on at least its inside surface with a heat-activated adhesive. The seamed liner was inserted into the stent-like support component, and the liner was inflated until the two non-seamed portions of the liner and the radially extending portions. . .

CLAIMS:

CLMS(1)

I claim:

1. A multiple-component branched expandable supportive endoluminal graft comprising:
a plurality of expandable supportive endoluminal components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;
one. . .

CLAIMS:

CLMS(2)

2. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is. . .

CLAIMS:

CLMS(3)

3. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are self-expanding.

CLAIMS:

CLMS(4)

4. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are deployed by a radially expandable device.

CLAIMS:

CLMS(5)

5. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive component includes a generally cylindrical supporting member and a generally. . .

CLAIMS:

CLMS(6)

6. The supportive endoluminal graft in accordance with claim 1, wherein said trunk liner is a stretchable wall of essentially inert biocompatible material, said stretchable. . .

CLAIMS:

CLMS(7)

7. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the generally cylindrical supportive leg component is a stretchable wall of. . .

CLAIMS:

CLMS(8)

8. The supportive endoluminal graft in accordance with claim 1, wherein said at least two leg portions of the trunk liner are partially defined by. . .

CLAIMS:

CLMS(9)

9. The supportive endoluminal graft in accordance with claim 8, wherein said leg portions are further defined by portions of the trunk liner which are. . .

CLAIMS:

CLMS(10)

10. The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner are longitudinally generally coextensive with a central. . .

CLAIMS:

CLMS(11)

11. The supportive endoluminal graft in accordance with claim 10, wherein an outside section of each of said leg portions of the trunk liner is. . .

CLAIMS:

CLMS(12)

12. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component, when

deployed, is telescopically slidably positioned within one. . .

CLAIMS:

CLMS(13)

13. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the leg component and said trunk liner are each a stretchable. . .

CLAIMS:

CLMS(14)

14. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of each stretchable wall is an elastomeric polymer.

CLAIMS:

CLMS(15)

15. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of said stretchable wall is a polycarbonate urethane.

CLAIMS:

CLMS(16)

16. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material is coated with a thin layer of silicone rubber.

CLAIMS:

CLMS(17)

17. The supportive endoluminal graft in accordance with claim 5, wherein said trunk liner and said liner of the leg component are each a stretchable. . .

CLAIMS:

CLMS(18)

18. The supportive endoluminal graft in accordance with claim 1, wherein an exposed longitudinal end of said tubular supporting member extends longitudinally beyond and is. . .

CLAIMS:

CLMS(19)

19. The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting component includes a plurality of wire strands with open areas therebetween.

CLAIMS:

CLMS(20)

20. The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are generally sinusoidally configured wire that. . .

CLAIMS:

CLMS(21)

21. The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are shaped as intersecting elongated lengths. . .

CLAIMS:

CLMS(22)

22. The supportive endoluminal graft in accordance with claim 1, wherein said trunk component includes a projecting securement member.

CLAIMS:

CLMS(23)

23. A multiple-component branching expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal graft components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible and radially expansible;
one of said expandable supportive endoluminal graft components being a trunk component having a longitudinal axis, an internal liner including a seam disposed generally along the longitudinal. . . flank said seam and which extend in opposite directions from said legs;
at least one other of said expandable supportive endoluminal graft components being a generally cylindrical supportive leg component;
said trunk component liner being a stretchable wall of essentially inert biocompatible material,. . .

CLAIMS:

CLMS(24)

24. The branching graft according to claim 23, wherein said trunk component has a network of land areas with open areas defined therebetween.

CLAIMS:

CLMS(25)

25. A method for making a multi-component bifurcating expandable supportive endoluminal graft, comprising the steps of:
providing a generally tubular self-supporting member;
providing a generally cylindrical liner made of flexible material, and flattening. . .

CLAIMS:

CLMS(26)

26. The method of claim 25 further including providing a further expandable supportive endoluminal graft component by providing a generally cylindrical supportive leg component which is sized to be telescopically assembled with one of the. . .

US PAT NO: 5,849,035 [IMAGE AVAILABLE] L1: 4 of 37

SUMMARY:

BSUM(7)

Typically, . . . fluid. In that method, heat is conducted from the fluid in the balloon, through the balloon material, and into the stent. Since conduction is a relatively slow process and the balloon has a relative large thermal mass, energy is transferred not only to the stent, but also to the surrounding body tissues and fluids. The result is that undesired amounts of heat are transferred into. . .

SUMMARY:

BSUM(13)

The resulting shaped article provides a therapeutic benefit by acting, in one embodiment, as a stent to maintain patency through a blood vessel. Numerous other therapeutic shapes are contemplated as well.

DETDESC:

DETD(36)
G. Polyoxyalkylenes, where alkene is 1 to 4 carbons, as homopolymers and copolymers including graft copolymers.

DETDESC:

DETD(64)

In one embodiment, the polymeric material may comprise a stent that is applied to the interior of a blood vessel following treatment of a stenosis by angioplasty. In that embodiment,. . .

DETDESC:

DETD(97)

The . . . is guided to a treatment location. Alternatively, other mechanical means such as end caps, or other retainers known in the stent art may be used to retain the article on the balloon. In particular, retaining sleeves or grommets of silicone or. . .

DETDESC:

DETD(116)

For . . . foreign material (i.e., polymer) placed into the blood vessel. Perforations may encourage more rapid and complete encapsulation of the polymeric stent, which may be desired to prevent distal embolization.

DETDESC:

DETD(117)

The . . . surfaces to prevent the formation of connective tissue following trauma or surgical injury, or the material may be used to adhere tissue surfaces to other tissues or implants. In one embodiment, the adherent properties of the materials may be used to join severed nerve endings. These and other applications are described in detail. . .

DETDESC:

DETD(140)

Devices, . . . (1050 micron) mandrel to obtain a roll about 10 mm long along the mandrel. The roll was secured with Teflon tape and heat set at 50 degrees C at least 12 hours. The rolled devices were cold sterilized with ethylene oxide. . .

US PAT NO: 5,833,650 [IMAGE AVAILABLE] L1: 5 of 37

DRAWING DESC:

DRWD(11)

FIG. . . . the distal extremity of another embodiment of a catheter apparatus incorporating the present invention and utilized for delivering an expandable stent to a stenosis.

DETDESC:

DETD(2)

More . . . first balloon 19 can be formed as a separate balloon separate from the elongate tubular member 16 as shown and adhered thereto by suitable means such as an adhesive (not shown), or it can be formed integral with the tubular member. . .

DETDESC:

DETD(10)

The . . . with an occlusion formed by a stenosis in a vessel not having a bifurcation therein as for example in saphenous graft or in one of the right and left carotid arteries, also called internal and external carotid arteries, of a patient. . .

DETDESC:

DETD(22)

Atherectomy . . . 9 onto the distal extremity of the tubular member 86. The flexible elongate member 107 can be formed of a ribbon having a thickness of 0.003" and a width of 0.060". One end of the flexible elongate member 107 can be. . .

DETDESC:

DETD(26)

In order to ensure that restenosis will not take place, it may be desirable to place a cylindrical stent 126 in the stenosis 76. Such a stent 126 can be a self-expanding stent formed of a suitable material such as a superelastic Nitinol and movable between unexpanded and expanded conditions. Such a stent 126 can be placed by a suitable catheter apparatus 131 of the type shown in FIG. 10. The stent 126 which is cylindrical in form is pushed over the proximal extremity of the second elongate flexible tubular member 31. . . to facilitate pushing of the flexible elongate tubular member 136 so that its distal extremity is in engagement with the stent 126. Thus, when desired the stent 126 may be discharged or dislodged from the distal extremity of the second tubular member 31 and pushed into the. . .

DETDESC:

DETD(27)

After the stent 126 has been discharged out of the end of the first flexible elongate tubular member 16, the stent 126 will self expand toward its expanded condition until it is in engagement with the wall of

the vessel in the vicinity of the occlusion forming the stenosis 76 to frictionally retain the stent in engagement with the vessel wall. As soon as the stent 126 is in engagement with the vessel wall, the second balloon 36 can be deflated as can the first balloon 19. The first deflated balloon 36 can then be withdrawn through the interior of the cylindrical stent 126. This can be followed by deflation of the first balloon 19 and the removal of the flexible elongate tubular. . .

DETDESC:

DETD(48)

As . . . deploying stents. Where that is desirable the apparatus of the present invention, perfusion can be accomplished during employment of the stent.

CLAIMS:

CLMS(2)

2. The method of claim 1, wherein said blood vessel is a saphenous vein graft.

US PAT NO: 5,833,593 [IMAGE AVAILABLE] L1: 6 of 37

SUMMARY:

BSUM(7)

A . . . in order to ideally fuse together fragmented segments of tissue. U.S. Pat. No. 4,733,655 to Palmaz discloses an expansible vascular graft which is expanded within a blood vessel by an angioplasty balloon to dilate and expand the lumen of the blood vessel. The Palmaz method and apparatus leaves the expandable vascular graft in place to ideally prevent recurrence of stenosis in the body passageway.

SUMMARY:

BSUM(11)

Two . . . to reduce restenosis. One approach involves the use of a revascularization device, such as the laser catheter, thermal catheter or stent to debulk plaque and create a smooth lumen to minimize turbulence and platelet aggregation along the vessel wall.

DETDESC:

DETD(24)

FIG. . . . plug 490 can be easily and inexpensively implanted, as for example, by using a long needle to inject an epoxy glue into the proximal end of the lumen of unmodified section 180. Plug 490 may also be a flexible seal composed of a flexible material such as latex that has been glued in place at or about the junction of unmodified section 180 and tapered section 275.

DETDESC:

DETD(31)

The . . . high purity aluminum such as aluminum 1100, platinum, or the titanium/nickel alloy described previously) with both ends welded, soldered, or glued closed. In a preferred embodiment the iridium will be encapsulated before it is irradiated to form Ir-192 and the capsule. . .

DETDESC:

DETD(33)

One . . . gold, titanium, platinum, etc. The coating may also be made of a non-metallic material such as a hardening agent (e.g., glue or acrylic). The coating may be applied to core 660 by brushing, dipping, painting or molecularly bonding the coating material. . .

DETDESC:

DETD(55)

Next . . . is inserted from the proximal end until it touches the rounded end 780 of backbone wire 720. A mark or tape is placed on the measuring wire at the point where the wire is exiting the tubing. The measuring wire is. . .

DETDESC:

DETD(58)

One . . . end of the wire is measured. The backbone wire is than advanced out the proximal end and a slow drying glue or epoxy can be applied to the backbone wire a couple of centimeters distal to the rounded end 780. The. . . backbone wire is cut flush to the distal end 150 where it exits the tubing and is welded, soldered, epoxyed, glued, etc. permanently to the tubing. This end is then rounded.

DETDESC:

DETD(59)

Alternatively, . . . of radioactive particles and as a safety wire if the outer housing material should break along unmodified section 180. If glue or epoxy is used, once it has dried, the cavity may be cleared of any residue glue or epoxy by reaming, drilling, honing, grinding, etc.

DETDESC:

DETD(62)

Alternatively, . . . or 595 can be permanently fixed to the housing material by means of spot welding, or by applying a slow-drying glue, epoxy, etc. to the plug prior to loading it into position. The temporary backbone wire is removed after the spot welding takes place or prior to the glue or epoxy permanently hardening into position.

DETDESC:

DETD(63)

Another . . . be removed and a small piece of hardening agent that would have a low melting temperature, such as solder or glue (such as the glue used for hot glue guns), would be loaded and advance from the distal end by means of the backbone wire until the hardening agent. . .

DETDESC:

DETD(65)

Attachment . . . of the wire and welded to the housing tube to seal the distal end of the backbone wire 820. Any glue adhering to the internal surface of the proximal portion of the housing tube, where the epoxied backbone wire was drawn. . .

DETDESC:

DETD(67)

Another . . . and position distal to or at the bottom of the tapered section 275. Once again, depending on the material used, glue, epoxy, solder, welding, etc. could be used to hold the material into position.

US PAT NO: 5,824,046 [IMAGE AVAILABLE] L1: 7 of 37
TITLE: Covered stent

ABSTRACT:
A composite intraluminal device is deployable within a body vessel. The composite device includes an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis. A stent cover is formed of unsintered ePTFE which is expandable. The stent cover is positioned about the stent so as to permit expansion of the cover upon the radial expansion of the stent.

SUMMARY:

BSUM(2)

The . . . relates generally to an implantable intraluminal device. More particularly, the present invention relates to a composite intraluminal device including a stent and stent cover.

SUMMARY:

BSUM(4)

It . . . endoprostheses for the treatment of diseases of various body vessels. One type of endoprosthesis is commonly referred to as a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful in the treatment of stenosis, strictures or. . .

SUMMARY:

BSUM(5)

Stents generally include an open flexible configuration. This configuration allows the stent to be inserted through curved vessels. Furthermore, the stent configuration allows the stent to be configured in a radially compressed state for intraluminal catheter implantation. Once properly positioned adjacent the damaged vessel, the stent is radially expanded so as to support and reinforce the vessel. Radial expansion of the stent may be accomplished by inflation of a balloon attached to the catheter or the stent may be of the self-expanding variety which will radially expand once deployed. Examples of various stent constructions are shown in U.S. Pat. Nos. 4,503,569 to Dotter; 4,733,665 to Palmaz; 4,856,561 to Hillstead; 4,580,568 to Gianturco; 4,732,152. . . 4,886,062 to Wiktor, each of which are incorporated by reference herein. Additionally, published PCT WO96/26689 entitled "Improved Longitudinally Flexible Expandable Stent", and its priority U.S. applications 08/396,569 filed Mar. 1, 1995 and 08/511,076 filed Aug. 3, 1995 are also incorporated by. . .

SUMMARY:

BSUM(6)

While . . . adequately for the purpose of holding open otherwise blocked, weakened or occluded vessels, due to the open nature of the stent there is a tendency for the stent to permit passage of material through the body of the stent. Such material may include excessive cell or tissue growth (intimal hyperplasia), thrombus formations and plaque in vascular situations and tumors. . .

SUMMARY:

BSUM(7)

One technique to reduce the susceptibility for materials to pass through the wall of the deployed stent includes providing a composite intraluminal device including a stent and an outer covering which would surround the open stent construction. While such covers would prevent material from passing through the stent wall, the covering itself must be sufficiently flexible and expandable so as to permit deployment of the stent from its compressed condition to its radially expanded condition.

SUMMARY:

BSUM(9)

U.S. Pat. No. 5,123,916 to Lee describes in expandable intraluminal vascular graft which includes concentric cylindrical tubes having a plurality of scaffold members mounted there between. The scaffold members are expandable, ring-like and provide circumferential rigidity to the graft.

SUMMARY:

BSUM(11)

U.S. Pat. No. 5,389,106 to Tower discloses an impermeable expandable intravascular stent. An impermeable deformable membrane interconnects portions of a distensible frame to form an impermeable exterior wall to the frame. The. . . polymer and the frame is made from a fine wire of annealed platinum. The distensible frame may be an expandable stent and the membrane is a hypoallergenic biologically inert material that is free of latex rubber proteins. The membrane should be. . . protection. No specific classes of materials are mentioned except the product name Tactylon.RTM.. The impermeable membrane is attached to the stent by dipping the stent into the polymer solution of the membrane and subsequently drying the device to remove the solvent. The stent is imbedded within the membrane surface.

SUMMARY:

BSUM(12)

Another type of covered stent which permits radial expansion is shown in WO 96/00103 having an international publication date of Jan. 4, 1996. As shown and described therein, a metallic expandable stent includes an outer covering of ePTFE. The ePTFE cover exhibits suitable expansion capabilities so as to enable the cover to expand upon expansion of the underlying stent. However, in order to impart the expandable characteristics to the ePTFE cover, during formation the ePTFE material forming the cover. . . is required in order for the cover to exhibit sufficient expansion capabilities. It is therefore desirable to provide a covered stent where the cover is radially expandable with the stent and where the cover may be easily manufactured and applied to the stent.

SUMMARY:

BSUM(14)

It is an object of the present invention to provide an intralurninal prosthetic device such as a stent which will hold open an occluded, weakened or damaged vessel.

SUMMARY:

BSUM(15)

It is a further object of the present invention to provide a covered stent for intraluminal use which is designed to hold open a damaged lumen and to prevent material passage through the body of the stent.

SUMMARY:

BSUM(16)

It is a still further object of the present invention to provide an expandable covered stent which may be deployed intraluminally wherein the cover of the stent expands with the expansion of the stent.

SUMMARY:

BSUM(17)

In . . . attainment of these and other objects, the present invention provides a composite intraluminal device including an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis. A stent cover is formed of unsintered ePTFE which is expandable and which is positioned about the stent for expansion with the radial expansion of the stent.

SUMMARY:

BSUM(18)

In one preferred embodiment, the stent cover includes a longitudinal segment of unsintered ePTFE generally aligned longitudinally along the longitudinal stent axis. The longitudinal segment is expandable in a transverse direction upon radial expansion of the stent.

SUMMARY:

BSUM(19)

In a further embodiment of the invention, the stent cover includes an elongate segment of unsintered ePTFE having an original longitudinal expanse. The segment is expanded in a transverse direction so as to reduce the original longitudinal expanse. The cover is positioned generally transverse to the longitudinal stent axis. The expanded segment is expandable longitudinally upon radial expansion of the stent to return the expanded segment to the original longitudinal expanse to control the radial expansion of the stent. Further in this embodiment, the cover may be positioned with respect to the stent in a manner where the longitudinal stent axis lays orthogonally (i.e. at an acute off axis angle) with respect to the cover.

SUMMARY:

BSUM(20)

In . . . provides a method of forming an intraluminal device. The method includes the step of providing an elongate radially expandable tubular stent. An elongate stent cover is formed of unsintered ePTFE. The stent cover is expandable in a transverse direction. The stent cover is applied about the stent with the stent cover longitudinally aligned with the stent so as to prevent transverse expansion of the cover upon radial expansion of the stent.

DRAWING DESC:

DRWD(3)

FIG. 2 is a perspective showing of a stent of the type which may be used in the composite device shown in FIG. 1.

DRAWING DESC:

DRWD(4)

FIG. 3 is a perspective showing of a stent cover employed in the composite device shown in FIG. 1.

DRAWING DESC:

DRWD(6)

FIG. 4 is a cross-sectional view of one embodiment of the covered stent of the present invention shown in the compressed condition.

DRAWING DESC:

DRWD(7)

FIG. 5 is a cross-sectional view of the covered stent of FIG. 3 shown in the radially expanded condition.

DRAWING DESC:

DRWD(11)

FIG. 8 is a schematic representation of the cover of FIG. 6 applied about the stent.

DRAWING DESC:

DRWD(13)

FIG. 10 is a cross-sectional view of the covered stent of FIG. 8 in the radially expanded condition.

DRAWING DESC:

DRWD(14)

FIG. 11 is a graft illustrating the properties of the material forming the cover of the device of the present invention.

DETDESC:

DETD(2)

The present invention provides a composite covered stent which may be implanted intraluminally within a body vessel and disposed adjacent an occluded, weakened or otherwise damaged portion of the vessel so as to hold the vessel open. The covered stent is typically delivered intraluminally via a balloon catheter. The device is delivered in a compressed condition and once properly positioned. . . the intraluminal device is by balloon expansion, however, the present invention may also be deployed by use of a self-expanding stent.

DETDESC:

DETD(3)

The composite intraluminal device 1 of the present invention takes the form of a stent 10 which may be of the type shown in FIG. 1 and a liner or cover 12 which may be of the type shown in FIG. 3. In use in a preferred arrangement the cover 12 is disposed over stent 10.

DETDESC:

DETD(4)

Referring specifically to FIG. 2, stent 10 is generally an elongate tube having a longitudinal stent axis l.sub.s. Stent 10 has opposed open ends 10a and 10b and a central lumen 10c therebetween. The body of stent 10 defines an opposed interior surface 11 and exterior surface 13 and is formed of a generally open configuration having a plurality of openings or passages through the body. These openings or passages provide for longitudinal flexibility of the stent as well as permitting the stent to be radially expanded once deployed in the body lumen.

DETDESC:

DETD(5)

The stent of the present invention is of the type more fully shown and described in International Patent Application No. WO 96/03092A1. . . No. 282,181 filed Jul. 28, 1994 and Ser. No. 457,354 filed May 31, 1995, are incorporated by reference herein. The stent shown therein has a patterned shape having first and second meandering patterns extending orthogonally to each other. The particular meandering pattern and the opening or spaces therebetween allows the stent to be easily deployed through curved blood vessels as it renders the stent longitudinally flexible. Furthermore, the particular configuration of the stent 10 disclosed herein allows the stent to be radially expanded without significant reduction in longitudinal expanse.

DETDESC:

DETD(6)

While the present invention discloses a particular construction of stent 10, any open stent configuration well known in the prior art may be employed. For example, wire stents having bodies formed of helically coiled. . .

DETDESC:

DETD(7)

Stent 10 may be employed in combination with liner or cover 12 shown in FIG. 3. Cover 12 may be applied, in a preferred embodiment, over tubular stent 10 so as to fully circumferentially surround stent 10. While the preferred embodiment contemplates employing cover 12 about the exterior surface 13 of stent 10 as shown in FIG. 1, it is also contemplated that cover 12 in the form of a liner may be placed about the interior surface 11 of stent 10. The cover 12 thereby forms an effective barrier about stent 10 preventing excessive cell or tissue ingrowth or thrombus formation through the expanded wall of tubular stent 10. However, in order for cover 12 to function effectively in combination with stent 10, cover 12 must exhibit sufficient expansion capabilities so as to enable the cover 12 to expand along with the radial expansion of stent 10.

DETDESC:

DETD(8)

The present invention contemplates use of a polymer material for cover 12 which exhibits sufficient expansion capabilities once positioned about stent 10. Such materials include extrudable, biocompatible polymers which exhibit or can be formed with a high degree of molecular orientation. . .

DETDESC:

DETD(11)

It . . . certain commercially available PTFE materials exhibiting such properties may be employed in combination with the present invention. For instance, polytetrafluoroethylene tape may be used in combination with the present invention. The manufacture of such a tape is shown and described in U.S. Pat. No. 5,474,727 to Perez and U.S. Pat. No. 5,175,052 to Tokuda, each of which is incorporated by reference herein. The tape manufactured by the process described in the above-incorporated patents results in porous tape having little or no expansion capabilities in the longitudinal direction but exhibiting superior expansion capabilities in a direction substantially transverse. . .

DETDESC:

DETD(12)

In order to employ such ePTFE tape as a cover for a stent 10, a segment thereof forming cover 12 is provided. Referring to FIGS. 3-5, cover 12 is positioned so that its longitudinal expanse l.sub.1 aligns with the longitudinal stent axis l.sub.s of stent 10. In preferred form, the cover 12 is wrapped around the exterior surface of stent 10 so that opposed longitudinal edges 12a and 12b overlie each other forming a seam 14. Edges 12a and 12b may be adhered to one another so as to provide a closed seam. Adhering techniques such a compression or adhesive bonding or anchoring. . . as to form an adhesive bond between the overlapped edges 12a and 12b. While cover 12 is shown attached to stent 10 by bonding overlapped edges 12a, 12b to form seam 14, it is further contemplated that cover 12 may be adhered to stent 10 at one or more locations therealong. Such securement is shown and described in commonly assigned U.S. patent application Ser. No. 08/721,834 filed at an even date herewith (as attorney docket no. 760-2) and entitled "Stent/Membrane Composite Device" which is incorporated by reference herein.

DETDESC:

DETD(13)

Once positioned about compressed stent 10, the ability of the material forming cover 12 to expand in a transverse direction allows the cover to be radially expanded upon the radial expansion of stent 10. Upon such radial stent expansion, either by balloon inflation or by self-expanding capabilities, cover 12 will expand transversely from a transverse dimension t.sub.1 to. . . and 5, the transverse expanse t.sub.1 of cover 12 forms the circumferential component of the cover 12

about the compressed stent 10. Upon the radial expansion of stent 10, the ability for the transverse component of cover 12 to expand from a dimension t.sub.1 to a dimension t.sub.2 allows this cover to expand radially with the expansion of stent 10. Thus, as shown in FIG. 5, cover 12 expands to a circumferential dimension of t.sub.2 about expanded stent 10.

DETDESC:

DETD(15)

Referring . . . in a transverse direction. In this embodiment of the present invention, cover 12' is transversely expanded prior to placement about stent 10. As shown in FIG. 7, cover 12' is expanded transversely to a transverse dimension of t.sub.2 '. FIG. 6A. . . reduction in the longitudinal expanse of cover 12' to a dimension of l.sub.2 ' which is less than l.sub.1 '. Stent 10 is then aligned with cover 12 so that its longitudinal stent axis l.sub.s extends along the transverse dimension t.sub.2 ' of cover 12 as shown in FIG. 8. Cover 12' is then wrapped about stent 10 so that the transverse edges 12c' and 12d' overlap forming a closed seam 14. The overlapped transverse edges 12c. . .

DETDESC:

DETD(16)

While . . . upon longitudinal stretching, stretch back to its original length. By employing the material as so described, the radial expansion of stent 10 can be controlled.

DETDESC:

DETD(17)

As shown in FIG. 9, with the stent 10 positioned with respect to cover 12' as described with respect to FIG. 8, radial expansion of stent 10 from the compressed condition shown in FIG. 9 to the expanded condition shown in FIG. 10 results in a. . . expanded cover 12' is expandable along its longitudinal expanse only to its original length l.sub.1 ', the radial expansion of stent 12 supported thereunder will therefore be limited. Upon radial expansion of stent 12, the stent will only be expanded to an extent where cover 12' expands to a longitudinal dimension of l.sub.1 '. Further expansion of stent 10 is limited as cover 12 has reached its maximum expansion capability. By controlling the expansion properties of cover 12 control of the expansion of stent 10 may be achieved.

DETDESC:

DETD(18)

As cover 12' returns to its original length l.sub.1 ' upon expansion of stent 10, shortening of its transverse expanse t.sub.2 ' back to transverse expanse t.sub.1 ' will occur. This will result in shortening of the cover about the stent 10. Such effects of shortening can be reduced by placing stent 10 with the stent axis l.sub.s ' slightly orthogonal with respect to transverse extent t.sub.2 '. While still providing a limit to the expansion of stent 10, the adverse effects of shortening will be thereby reduced.

CLAIMS:

CLMS(1)

What is claimed is:

1. A composite intraluminal device comprising:
an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis; and
a stent cover positioned about the stent and which is formed of unsintered ePTFE which is expandable upon said radial expansion of said stent,
wherein said stent covering includes an elongate segment of said unsintered ePTFE having an original longitudinal expanse, said segmnent being expanded in a transverse direction so as to reduce said original longitudinal expanse, said segment being positioned generally transverse to said longitudinal stent axis, and being expandable longitudinally upon said radial expansion of said stent to return said expanded segment to said original longitudinal expanse to thereby control said radial expansion of said stent.

CLAIMS:

CLMS(2)

2. A composite intraluminal device of claim 1 wherein said stent is radially expandable from a first compressed state permitting intraluminal delivery to a second expanded state permitting intraluminal deployment.

CLAIMS:

CLMS(4)

4. A composite intraluminal device of claim 1 wherein said segment is joined about said stent along a seam formed by opposed overlapped transverse ends of said segment.

CLAIMS:

CLMS(5)

5. A method of forming an intraluminal device comprising the steps of:
providing an elongate radially expandable tubular stent;
forming a stent cover from a longitudinal segment of unsintered EPTFE having a first longitudinal expanse and a transverse expanse,
expanding said segment along. . . first transverse expanse and a second longitudinal expanse less than said first longitudinal expanse; and
applying said expanded segment about said stent, with said second transverse expanse extending longitudinally along said elongate stent.

CLAIMS:

CLMS(6)

6. A method in accordance with claim 5 wherein said applying step includes wrapping said cover exteriorly about said stent.

CLAIMS:

CLMS(7)

7. A method in accordance with claim 6 wherein said wrapping step further includes:
overlapping opposed longitudinal of said stent cover.

CLAIMS:

CLMS(8)

8. A method in accordance with claim 7 further including the step of:
securing said overlapped longitudinal ends of said stent cover together.

CLAIMS:

CLMS(11)

11. A method in accordance with claim 6 wherein said wrapping step includes:
wrapping said expanded segment about said stent with said second longitudinal expanse extending generally transverse to said elongate stent.

CLAIMS:

CLMS(12)

12. An intraluminal stent assembly comprising:
a radially expandable stent having a longitudinal stent axis;
a stent cover positioned about said stent and being formed of a generally uniaxially oriented polymer, said stent cover being oriented in a first direction and expanded in a second direction transverse to said first so as to decrease the length of said stent cover from its original length, said longitudinal axis of said stent being aligned with said second direction, so that said stent cover is expandable in said first direction to its original length upon said radial expansion of said stent to control said radial expanse of said stent.

CLAIMS:

CLMS(13)

13. A stent assembly of claim 12 wherein said expanded stent cover is expandable in its first direction up to its original length.

CLAIMS:

CLMS(14)

14. A stent assembly of claim 13 wherein said uniaxially oriented polymer includes unsintered ePTFE.

US PAT NO: 5,824,043 [IMAGE AVAILABLE] L1: 8 of 37
TITLE: Endoprosthesis having graft member and exposed welded end junctions, method and procedure

ABSTRACT:
An endoprosthesis is provided which includes a stent component and a graft component capturing a portion of the stent component. The stent component is made of generally malleable material arranged to provide the stent component with a collapsed transluminal positioning configuration and an expanded, deployed configuration. The stent component has adjacent end windings that are welded together. In a preferred arrangement, a plurality of these welds define a spine-like welded arrangement, and a number of these arrangements are positioned generally circumferentially around the ends of the stent component. The graft component extends generally between the welded end portions of the stent component, with limited overlap being possible. Also provided is a method for forming this endoprosthesis and a procedure by which. . .

SUMMARY:

BSUM(2)

The . . . generally relates to endoprostheses and to their preparation and use. More particularly, the invention relates to an endoprosthesis having a stent component with adjacent windings composed of undulating bendable segments that are oriented in a generally helical pattern along the length. . . to the endoprosthesis. A number of adjacent windings at each axial end portion of the endoprosthesis are welded together. A graft component closely overlies the outer and inner cylindrical surfaces of the stent component such that the axial end portions of the stent component are uncovered. The welded portions add rigidity to the endoprosthesis ends and assist in maintaining the position and patency. . .

SUMMARY:

BSUM(3)

Various so-called stent devices have been developed or proposed for use in association with angioplasty treatments and other medical treatments or procedures wherein devices having expandable components, such as balloon catheters, are used to treat a condition with a body vessel. The stent is in the nature of a device, usually tubular or cylindrical in shape, which is deployed by a balloon or. . . 5,133,732 proposes longitudinal over-stretch limiting means such as by attaching a longitudinal wire generally parallel to the axis of the stent.

SUMMARY:

BSUM(4)

Graft devices are also known, grafts being in the nature of woven, wound or molded cylinders or the like that are. . . surgical procedures. It has been proposed that grafts can be deployed through percutaneous placement by combining the features of a stent-like device with those of a graft. Deployment in this regard would be by way of a percutaneous transluminal angioplasy balloon or other device that can be. . . place for deployment purposes. One potential difficulty with these types of combination devices is a means for insuring that the graft will remain in place after deployment for extended lengths of time. It is particularly important that any anchoring arrangements also. . .

SUMMARY:

BSUM(5)

Endoprostheses . . . ability to be percutaneously and transluminally deployed with excellent patency while also affording good rigidity to certain portions of the stent component in order to enhance the anchoring attributes of the stent-like components of the device. Endoprostheses of the present invention also exhibit the ability to follow the contour of the vessel. . .

SUMMARY:

BSUM(6)

In . . . in an undulating fashion, which undulating strand is wound in a generally helical configuration to form the body of the stent portion of the endoprosthesis, same being composed of a plurality of full circle windings continuous with each other along the. . . adjacent end windings, preferably along a plurality of spinal weld patterns that

follow the contour of the adjacent windings. A graft component covers the central length of the stent component while a substantial portion of the welded end lengths protrude longitudinally beyond the graft component. Graft materials sandwich the central portion of the stent component between inner and outer walls of graft material. In an especially preferred embodiment for manufacturing the endoprosthesis, the inner graft member is spun onto a mandrel, the formed and welded stent component is placed thereover, and an outer graft member is spun over the central length of the stent component in a manner to effect adherence of the inner and outer graft members together to capture the stent member therebetween.

SUMMARY:

BSUM(7)

It is accordingly a general object of the present invention to provide an improved endoprosthesis having a graft component at its central portion and a welded stent component at its ends, as well as the making and use of same.

SUMMARY:

BSUM(9)

Another object of this invention is an improved endoprosthesis and procedure for deploying same which includes anchoring uncovered stent ends within a body vessel wall.

SUMMARY:

BSUM(11)

Another object of this invention is to provide an improved endoprosthesis and deployment procedure whereby stent spines add rigidity to endoprosthesis ends and maintain the position and patency of the graft of the endoprosthesis.

DETDESC:

DETD(4)

With more particular reference to the endoprosthesis 11, the illustrated embodiment includes a stent component 21 constructed of a strand of metal or polymer which exhibits malleability adequate to be formed into shapes such. . .

DETDESC:

DETD(5)

A . . . along the circumference of the endoprosthesis. Each such grouping or spine generally follows pitch angle "A", which substantially follows the graft helix that is defined by adjacent connecting portion pairs 17, 17 of adjacent windings.

DETDESC:

DETD(7)

As . . . is presented between the welded groupings as illustrated in the preferred embodiment. Generally speaking, the larger the circumference of the stent member, the greater the number of weld spines can be accommodated. Different spacings are also possible. It will be appreciated. . .

DETDESC:

DETD(10)

More . . . it is at present generally accepted that the supporting surface area (typically the "metal" outside or working surface of the stent) is to constitute between about 12% and about 15% of the cylindrical surface defined by the stent. Otherwise, inadequate support will be provided. This means that, under present beliefs, it is desirable to have between about 85% and about 88% open space presented by the external cylindrical definition of a stent component. The configuration of the welded end portions of the stent component of the invention is tailored to fall within these guidelines. More importantly, the amount of supportive surface area or "metal" presented to the vessel by the stent is a consistent percentage throughout the length and circumference of the welded ends. Accordingly, if 12 to 15% supporting surface. . .

DETDESC:

DETD(11)

With more particular reference to the welds 18 of the stent component 21 of the endoprosthesis, they are preferably formed by a fusion welding procedure, such as electron beam welding, laser. . .

DETDESC:

DETD(12)

Strand material out of which the stent component 21 of the endoprosthesis according to the invention is made must be capable of forming a joint under welding. . . high molecular weight polyethylenes, carbon fibers, Kevlar polymer, and the like. It is also possible to coat these materials after stent formation has been completed with porous or textured surfaces for cellular ingrowth and the like or with non-thrombogenic agents such. . . can also be carried out so that drugs or medicines can be eluted therefrom. It is also possible. that certain stent components may be made of biodegradable materials. The strand material must, of course, be biocompatible. Tantalum is the especially preferred. . .

DETDESC:

DETD(13)

In addition to the stent component 21, endoprostheses in accordance with the present invention include a graft component, generally designated as 22 in FIG. 4. Graft component 22 includes both an interior graft member 23 and an exterior graft member 24. The interior and exterior graft members typically have the same longitudinal length, although the exterior graft member 24 could be longer than the interior graft member 23 if desired. In essence, the interior graft member serves as an attachment base for the exterior graft member to incorporate the stent member therebetween.

DETDESC:

DETD(14)

While the graft component could be made of various different materials and in various different configurations, such as those which are woven, non-woven, spun, molded, extruded and the like, the preferred graft component has a non-woven, spun configuration. It is especially preferred that this material be made by a winding procedure such. . . as feed to the multiple-nozzle ejector 28. The combination of the rotating mandrel and reciprocating shuttle assembly forms the non-woven graft material illustrated wherein individual strands cross underlying strands. It will be appreciated that the spinnable polymer freshly extruded through the nozzles will lie down over and be generally adhered to underlying strands which had been previously laid down, particularly those which cross each other.

DETDESC:

DETD(15)

It . . . down these strands in a single helical pattern. In that event, an ejector having enough nozzles to lay down a ribbon formed of these strands during one pass can be used to lay down a helical internal ribbon in which event the shuttle would not be used. Whether a single helical pattern is used or crossing helical patterns. . . angle of the single helical pattern or of one of the helical patterns will approximate the pitch angle of the stent component. When the endoprosthesis is expanded, these pitch angles will accordingly enlarge, generally to about the same extent.

DETDESC:

DETD(16)

In the illustrated embodiment, the interior graft member 23 is first formed on the mandrel in accordance with the procedure illustrated in FIG. 2. Thereafter, the stent component 21 is fitted thereover. Typically, this can include trimming the interior graft member 23 to the desired length, after which the stent component is slid thereover while the graft member 23 is still on the mandrel. This approach is convenient for formation of the exterior graft member 24 directly onto the same mandrel by following substantially the same procedure as illustrated in FIG. 2. When thus laid down, it is preferred that the inner graft member strands and especially the outer graft member strands are not fully cured. As a result, bonding takes place between the strands of the inner and outer members throughout the length of the center of the stent component. The central length of the stent component is enveloped in or captured by the graft component 22 as generally shown in FIGS. 4 and 5. After assembly is complete, the edges of the graft component are preferably trimmed.

DETDESC:

DETD(17)

It is desired that the graft component overlap with the end lengths 19, 20 of the stent component. Preferably this overlap is such that a maximum of approximately twenty-five percent of the welds 18 of these end lengths are covered by the inner and outer graft material. This insures that the combination will be held together without buckling or pleating. Enough of the welded end lengths are to be uncovered, at least by the exterior graft member 24, so that a substantial portion of the end lengths expand without any significant constraint by the graft component to ensure full and uniform deployment of the welded end lengths as discussed herein. Superior stenting and anchoring result. In addition, a sufficient extent of the end lengths of the stent, component should be uncovered by the graft materials to facilitate having the graft ends maintain patency and proper endoprosthesis positioning. Uses in abdominal or aortic applications are especially suitable for these types of. . .

DETDESC:

DETD(18)

Materials suitable for making the graft component include polytetraethylene (PTE), EPTE, polytetrafluoroethylene, nylons, polyamides, as well as other polymers such as Gortex and Dacron fibers, bioabsorbables. . . of the same or different materials. Treatment materials such as drugs and anticoagulants may be incorporated, especially on the exterior graft member. When the graft component is to be a spun fiber component, it is important that the polymer be fiber forming in air so. . .

DETDESC:

DETD(19)

The formed graft component preferably is compliant enough to be able to readily follow the stent component, especially during its expansion, while also being of low elasticity so as to not significantly interfere with the ability of the stent component to maintain the endoprosthesis in its deployed condition. For example, a recoil of not greater than about 7 percent, preferably between about 5 and about 7 percent is suitable for a preferred graft material. Should the material exhibit inadequate compliance or excessive recoil or elasticity, the components of the endoprosthesis will tend to separate from one another, and/or develop ripples. Preferably, the graft member moves through its plastic state, or is plastically deformed, during endoprosthesis deployment so it will be stretched and expanded by the stent component and remain so after implantation is complete. Also graft structures, such as meshes, can exhibit elasticity due to the pattern of the fibrils. Whatever the graft member structure or material, the recoil force exerted on the stent component cannot be greater than the magnitude of radial force which will deform or collapse the stent component.

DETDESC:

DETD(20)

As discussed herein, the endoprosthesis of the invention can be deployed by means of a balloon catheter. Alternatively, the stent component and hence the endoprosthesis can be self-expanding. Such a stent component is made of nickel-titanium alloys or Nitinol alloys, or other materials which rapidly change in configuration or size when a temperature threshold is achieved. For example, a self-expanding endoprosthesis having a stent made of Nitinol alloy can be deployed into a blood vessel at an implantation diameter. When the treatment site is. . .

CLAIMS:

CLMS(1)

I . . .
an adjacent full circle winding to define a plurality of adjacent pairs of bendable connecting portions to thereby form a stent component having an interior surface and an exterior surface, said stent component having a central length portion between two end length portions, each said end length portion having a plurality of. . . portions of adjacent said full circle windings of the end length portions to form two welded end lengths; and
positioning a graft component along said interior and exterior surfaces of the stent component, including overlying an inner and outer member of the graft component over less than the entirety of the interior and exterior surfaces, respectively, of the stent component, said positioning step exposing a substantial axially

extending length of each of said two welded end length portions of the stent component such that the thus exposed welded end length portions are uncovered by the graft component, and said overlying of the positioning step includes overlying at least one welded full circle winding of both of. . .

CLAIMS:

CLMS(2)

2. The method in accordance with claim 1, wherein said step of positioning a graft component includes incorporating a central length of the stent component between the inner and outer members of the graft component and adhering said inner and outer members together.

CLAIMS:

CLMS(4)

4. . . . with claim 1, wherein said positioning step includes winding a plurality of fibers over said central length portion of the stent component.

CLAIMS:

CLMS(7)

7. . . . positioning step includes winding a plurality of fibers over a mandrel and positioning thereover said central length portion of the stent component.

CLAIMS:

CLMS(8)

8. . . . positioning step includes winding a plurality of fibers over a mandrel and positioning thereover said central length portion of the stent component, and said positioning step further includes winding a further plurality of fibers over said central length portion of the stent component.

US PAT NO: 5,817,126 [IMAGE AVAILABLE] L1: 9 of 37
TITLE: Compound stent

ABSTRACT:
A compound stent is disclosed, which includes a cylindrical member having first and second extremities and having a wall defining a central bore. . . between contracted and expanded conditions, the intermediate segment being formed of a braided material to impart greater flexibility to the stent along the longitudinal axis. Also, a method for making such a stent is disclosed, which includes steps of providing two complementary tubular pieces, each made up of an expandable stent segment from which a plurality of strands are attached by one end, then axially aligning the two pieces with the two stent segments at opposite ends and the strands between them, and moving the two pieces toward one another so that the. . .

SUMMARY:

BSUM(2)

This invention relates to stents and stent grafts for deployment within tubular anatomical structures within the body, for supporting the walls of the structures. Particularly the invention relates to expandable elongate flexible vascular stents and stent grafts.

SUMMARY:

BSUM(3)

Expandable stents and stent grafts are known in a wide variety of designs. These devices are made up of various arrangements of struts in. . .

SUMMARY:

BSUM(4)

Generally, an expandable stent or stent graft is passed into and through the lumen of the tubular structure (such as a blood vessel) in a collapsed (that is, unexpanded) condition until the treatment site is reached, and then the stent or stent graft is caused to expand (or is permitted or induced to expand) to contact and press against the lumenal surface of. . .

SUMMARY:

BSUM(5)

Where the particular treatment calls for a stent or stent graft of extended length, the device should be sufficiently flexible (at least in the collapsed configuration) to permit negotiation of curves within the vessel during deployment to the treatment site. At the same time, where the stent or stent graft is intended to prevent closure of the lumen of the vessel, the device in the expanded state should have sufficient. . .

SUMMARY:

BSUM(6)

One approach to providing for a stent graft of extended length and good radial strength is to connect two or more shorter inflexible stent segments in tandem by means of flexible connectors. Such an arrangement is described in co-pending U.S. patent application Ser. No. 08/818,274, titled "Stent", filed Mar. 17, 1997, which patent application is hereby incorporated herein in its entirety by reference. Such an assembly permits flex in the device between the tandemly arranged stent segments; it is not continuously flexible.

SUMMARY:

BSUM(8)

Braided . . . tissues, and can to some extent obstruct flow through the vessel. Moreover, it is desirable for the ends of the stent or graft to be smooth, to provide clean transition at the lumenal surface between the vessel wall and the ends of the graft. As one expedient, not fully satisfactory, the strands at the ends of braided grafts can be welded to reduce fraying.

SUMMARY:

BSUM(9)

One example of a treatment in which extended length grafts having substantial radial strength may be useful is a saphenous vein graft; here the condition being treated is a stenotic disease, and so substantial resistive force preventing the collapse of, or stenosis. . . and the aorta, particularly where the disease condition is a stenotic one and where it is desired to provide a stent for an extended segment of a vessel.

SUMMARY:

BSUM(11)

The invention provides for a cylindrically shaped expandable compound stent, including expandable stent segments at each end and an extended length expandable intermediate segment in the form of a braid of interlaced strands.

SUMMARY:

BSUM(12)

The intermediate segment provides continuous flexibility, and the stent segments provide for easy deployment of the device as well as for clean transitions between the lumenal surface of the. . .

SUMMARY:

BSUM(14)

In one general aspect the invention features a compound stent including a cylindrical member having an outside diameter, a length, and first and second extremities, and having a wall defining. . . between contracted and expanded conditions, the intermediate segment being formed of a braided material to impart greater flexibility to the stent along the longitudinal axis.

SUMMARY:

BSUM(15)

According to the invention, the compound stent can be constructed by making two complementary tubular pieces, each made up of an expandable stent segment from which a plurality of strands are attached by one end, then axially aligning the two pieces with the two stent segments at opposite ends and the strands between them, and moving the two pieces toward one another so that the. . .

SUMMARY:

BSUM(17)

In a second general aspect, then, the invention features a method for making a compound stent, by steps of providing a first part and a second part, each part having generally cylindrical shape with an outside. . . central bore having a longitudinal axis and extending from the first extremity to the second extremity, each part having a stent segment and a strand segment, the stent segment being formed of slotted material and being movable between contracted and expanded conditions, the strand segment including a plurality of strands each of which is connected by one end to the stent segment and has the other end free.

SUMMARY:

BSUM(18)

In some embodiments the strand segment and the stent segment are formed of the same slotted material; in preferred embodiments the material is a metal such as a stainless. . .

DRAWING DESC:

DRWD(4)

FIG. 1 is a sketch in a side view, showing a compound stent according to the invention.

DRAWING DESC:

DRWD(5)

FIGS. 2 and 3 are sketches showing complementary parts of a compound stent according to the invention which, when assembled according to the invention as described in more detail below, form the compound stent of FIG. 1.

DETDESC:

DETD(1)

Referring now to FIG. 1, a compound stent according to the invention is shown generally at 10 in an expanded condition as if deployed in a vessel (not shown in the Figure). Compound stent 10 includes a generally cylindrical member 11 having an outside diameter represented by the dimension D in FIG. 1 and. . .

DETDESC:

DETD(2)

The dimensions of the compound stent differ for different uses. The expanded diameter D, for example, is selected according to the inner diameter of the particular. . .

DETDESC:

DETD(6)

At . . . 40 is an expandable, flexible, generally cylindrical intermediate segment 60. Middle segment 60 is formed of a plurality of interlaced ribbon elements or strands, three of which are indicated by way of example at 62 in the Figures, and another three. . . first ends 65 of certain other of the strands (64, for example) are attached at attachment points 42 on second stent segment 40.

DETDESC:

DETD(7)

Each of first end segment 20 and second end segment 40 can be an expandable stent of any desired configuration.

DETDESC:

DETD(8)

The particular expandable stent segments 20, 40 shown in an expanded condition by way of example in the figures, have generally longitudinally oriented ribs (for example 21) which are connected generally circumferentially around the cylindrical shape of the stent segment with struts (for example, 23). Such a stent segment can be made according to any of various methods well known in the art, as described in more detail in my copending U.S. patent application Ser. No. 08/818,274 entitled "Stent", filed Mar. 17, 1997, referenced above.

DETDESC:

DETD(10)

The structure of the compound stent according to the invention, as well as the method of making it, may be described with reference to FIGS. 2 and 3. FIGS. 2 and 3 show complementary parts of a compound stent according to the invention which, when assembled as described below, form the compound stent illustrated in FIG. 1.

DETDESC:

DETD(18)

Usually . . . of over-and-under passes will be followed for all the strands. It is not necessary however, that a strict pattern be adhered to, or that all the strands be woven according to the same pattern.

DETDESC:

DETD(20)

Each . . . shorten as well, depending upon their design; as detailed in my copending U.S. patent application filed Mar. 17, 1997, titled "Stent", referenced above, the particular configuration of ribs and struts in the stent segments 20, 40 shown by way of example in the Figures herein have the advantage that they do not change. . .

DETDESC:

DETD(21)

A . . . by use of conventional etching or laser cutting techniques. This process is generally described, with reference to construction of a stent as is shown for example herein to provide the expandable end segments, in my copending U.S. patent application Ser. No. 08/818,274 filed Mar. 17, 1997, entitled "Stent", referenced above.

DETDESC:

DETD(22)

For . . . the first parts 14 can be made by cutting a first piece of the tubular material, to provide an expandable stent segment at both ends and a set of strands (if helical, then all turning in one direction); and then cutting. . . complementary second parts 16 can be made by cutting a second piece of the tubular material to provide an expandable stent segment at both ends and a set of strands (if helical, then all turning in the direction opposite that for. . .

DETDESC:

DETD(23)

An . . . method, a cylindrical member is cut as described above from a piece of the tubular material, to provide an expandable stent segment at both ends and a set of strands (if helical, then all turning in one direction). Then the weaving. . .

DETDESC:

DETD(24)

The compound stent according to the invention can be deployed in a conventional manner into the desired location. For example it can be deployed on a balloon catheter, by placing the compound stent onto the deflated balloon, using the balloon catheter to carry the compound stent to the desired site, and thereafter inflating the balloon to expand the stent into the desired size, after which the balloon can be deflated and removed. Similarly, if the compound stent is formed of a self-expanding material, the stent can be deployed by use of an appropriate stent deployment catheter, after which the stent can be released to expand to the maximum desired diameter, after which the catheter deployment mechanism can be removed.

CLAIMS:

CLMS(1)

What is claimed:

1. A compound stent comprising a cylindrical member having a length and first and second extremities and having a wall defining a central bore. . .

CLAIMS:

CLMS(2)

2. The stent of claim 1 wherein said intermediate segment is formed of the same material as the first and second segments.

CLAIMS:

CLMS(3)

3. The compound stent of claim 1 wherein said outside diameter when in said expanded condition is in the range about 1 mm to. . .

CLAIMS:

CLMS(4)

4. The compound stent of claim 1 wherein said length when in said expanded condition is in the range about 5 mm to about. . .

CLAIMS:

CLMS(5)

5. The compound stent of claim 1 wherein the thickness of said wall is in the range about 0.001" to about 0.02".

CLAIMS:

CLMS(6)

6. The compound stent of claim 1 wherein said diameter in said expanded condition is in the range about 1.5 mm to about 4. . .

CLAIMS:

CLMS(7)

7. The compound stent of claim 1 wherein said diameter in said expanded condition is in the range about 5 mm to about 10. . .

CLAIMS:

CLMS(8)

8. The compound stent of claim 1 wherein said diameter in said expanded condition is in the range about 1 mm to about 4. . .

CLAIMS:

CLMS(9)

9. The compound stent of claim 1 wherein said diameter in said expanded condition is in the range about 1 mm to about 4. . .

CLAIMS:

CLMS(10)

10. The compound stent of claim 1 wherein said material comprises a metal.

CLAIMS:

CLMS(11)

11. The compound stent of claim 10 wherein said metal comprises a stainless steel.

CLAIMS:

CLMS(12)

12. The compound stent of claim 10 wherein said metal comprises a nickel-titanium alloy.

CLAIMS:

CLMS(13)

13. The compound stent of claim 1 wherein said material comprises a plastic.

CLAIMS:

CLMS(14)

14. The compound stent of claim 1 wherein said braided material

comprises a metal.

CLAIMS:

CLMS(15)

15. The compound stent of claim 14 wherein said metal comprises a stainless steel.

CLAIMS:

CLMS(16)

16. The compound stent of claim 14 wherein said metal comprises a nickel-titanium alloy.

CLAIMS:

CLMS(17)

17. The compound stent of claim 14 wherein said material comprises a plastic.

CLAIMS:

CLMS(18)

18. The compound stent of claim 1 wherein said material comprises a laminate selected from the group consisting of nitinol/stainless steel laminate, platinum/stainless steel. . .

CLAIMS:

CLMS(19)

19. The compound stent of claim 1 wherein said intermediate segment comprises a plurality of interlaced strands.

CLAIMS:

CLMS(20)

20. The compound stent of claim 19 wherein said strands are of a metal or plastic material.

CLAIMS:

CLMS(21)

21. The compound stent of claim 20 wherein said strands are all of the same material.

CLAIMS:

CLMS(22)

22. The compound stent of claim 19 wherein said intermediate segment comprises a plurality of strands in a braided arrangement.

CLAIMS:

CLMS(23)

23. The compound stent of claim 22 wherein said intermediate segment comprises a braided arrangement of from 8-24 strands.

CLAIMS:

CLMS(24)

24. The compound stent of claim 23 wherein said intermediate segment comprises a braided arrangement of from 12-20 strands.

CLAIMS:

CLMS(25)

25. The compound stent of claim 19 wherein each of said strands is attached to one of said end segments.

CLAIMS:

CLMS(26)

26. The compound stent of claim 19 wherein each of said strands is attached to both of said first and second end segments.

US PAT NO: 5,810,870 [IMAGE AVAILABLE] L1: 10 of 37
TITLE: Intraluminal stent graft

ABSTRACT:
A tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene which is less than 0.10 mm thick. The covering may be on the exterior surface of the stent, or on the interior surface of the stent, or both. The covering may be affixed to the stent by an adhesive which is preferably fluorinated ethylene propylene.

SUMMARY:

BSUM(5)

Alternative methods have evolved which use intraluminal vascular grafts in the form of adjustable stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by. . .

SUMMARY:

BSUM(6)

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

SUMMARY:

BSUM(8)

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at. . . location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of adjustable stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

SUMMARY:

BSUM(9)

Intraluminal . . . No. 3,657,744 to Ersek describes a method of using one or more adjustable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

SUMMARY:

BSUM(10)

Choudhury, U.S. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terephthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

SUMMARY:

BSUM(11)

Rhodes, . . . sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX.RTM. Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff Ariz.) or Impra.RTM. Graft (Impra, Inc. Tempe Ariz.). Both the GORE-TEX Vascular Graft and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra graft as the sleeve component is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the. . . insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of manufacturing an extruded, longitudinally expanded. . .

SUMMARY:

BSUM(13)

The present invention is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular covering of porous expanded PTFE film affixed to the stent, said covering being less than about 0.10 mm thick.

SUMMARY:

BSUM(14)

Porous . . . type as taught by U.S. Pat. No. 4,776,337 which typically require a balloon catheter to increase the diameter of the stent within a blood vessel. The term self-expanding refers to stents which increase in diameter by various other means. Stents of. . .

SUMMARY:

BSUM(15)

The . . . covering of porous expanded PTFE film may be affixed to either the exterior surface or the luminal surface of the stent. Alternatively, a first tubular covering of porous expanded PTFE film may be affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded PTFE film may be affixed to the luminal surface of the tubular diametrically adjustable stent. The first and second tubular coverings of porous expanded PTFE film may be affixed to each other through the openings through the wall of the stent.

SUMMARY:

BSUM(16)

The porous expanded PTFE film may be affixed to the stent with an adhesive. The adhesive may be a thermoplastic adhesive and more preferably a thermoplastic fluoropolymer adhesive such as fluorinated. . . and second tubular coverings of expanded PTFE film are affixed to each other through the multiplicity of openings in the stent wall, the two coverings may be affixed by heating them above the crystalline melt point of the PTFE film adequately to cause them to thermally adhere, or alternatively they may be affixed by an adhesive such as FEP.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent.

DRAWING DESC:

DRWD(5)

FIG. 4 is a transverse cross section of the stent of Example 1 having a luminal layer of porous expanded PTFE film with longitudinally-oriented fibrils and an exterior layer of. . .

DRAWING DESC:

DRWD(6)

FIG. 5 is a transverse cross section of the stent of Example 2 having a luminal layer of porous expanded PTFE film with biaxially-oriented fibrils.

DRAWING DESC:

DRWD(7)

FIG. 6 is a transverse cross section of the stent of Example 3 having an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

DRAWING DESC:

DRWD(8)

FIG. 7 describes a method of collapsing a previously outwardly adjusted balloon-expandable stent.

DRAWING DESC:

DRWD(9)

FIG. 8 describes the fitting of a single tubular sleeve to both the

exterior and luminal surfaces of a stent.

DRAWING DESC:

DRWD(10)

FIG. 9 describes the removal a covered, braided wire stent of the self-expanding type from a manufacturing mandrel by everting the braided wire, thereby placing the covering on the luminal surface of the stent.

DETDESC:

DETD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. While the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be. . .

DETDESC:

DETD(3)

The stent may be provided with an exterior covering of porous expanded PTFE film, or a luminal covering of porous expanded PTFE. . .

DETDESC:

DETD(6)

Wall thickness measurements of intraluminal graft stent coverings were determined by cutting away a portion of the covering that covered an opening through the stent wall. The thickness of the sample portion was measured by placing the sample portion between the pads of a Mitutoyo. . .

DETDESC:

DETD(7)

The following examples of intraluminal stent grafts are intended to be illustrative only and are not intended to limit the scope of the invention to only. . .

DETDESC:

DETD(9)

A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film. This 3 cm long stent was formed from 0.25 mm diameter Nitinol wire into a tubular shape of interlocking hexagons. The luminal and exterior coverings. . . to each other. The luminal covering was provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering was provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the luminal and exterior coverings was a porous expanded PTFE film having a discontinuous, porous. . .

DETDESC:

DETD(17)

A . . . axis of the mandrel; the FEP-coated side of the film faced away from the surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The 3 cm length of the stent was centered over the 3.0 cm length of film-wrapped mandrel. The stent was then provided with an exterior covering 47 of a 3.0 cm wide tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so that the edges of the circumferentially-wrapped tape overlapped by about 3 mm to form seam 49. The circumferentially wrapped covering was oriented so that the FEP-coated side of the tape faced inward in contact with the exterior surface of the stent and the outward facing FEP-coated surface of the luminal layer of film exposed through the openings in the stent. Except for the overlapped seam edges 49, the circumferentially-wrapped covering was only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape were circumferentially-oriented about the exterior stent surface.

DETDESC:

DETD(18)

The . . . from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the film-wrapped stent. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the luminal layer of film was adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the stent. The combined thickness of the luminal and exterior coverings was about 0.025 mm.

DETDESC:

DETD(19)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(21)

A Nitinol wire stent of the same type used for Example 1 was provided with a luminal covering of a porous expanded PTFE film. . . had a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The mandrel assembly was then placed into an oven set. . . at 360.degree. C. for four minutes. After removal from the oven and subsequent cooling, the mandrel was removed from the stent leaving the wrapped film adhered to the luminal surface of the stent. This film was then peeled from the luminal stent surface, leaving the FEP-coating and some small shreds of residual porous expanded PTFE adhered to the luminal surface of the stent wires. By removing the film and leaving the FEP adhesive on the luminal stent surface, the film served only as a release substrate for the application of the adhesive to the stent surface.

DETDESC:

DETD(23)

The . . . contacted with the surface of a hand-held iron set at 400.degree. C. to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam was trimmed away and discarded. The stent was again carefully fitted over the film-covered mandrel. The resulting assembly was placed into an oven set at 380.degree. C. for three minutes and then removed and allowed to cool, after which the mandrel was removed from the stent. The porous expanded PTFE film appeared to be well adhered to the luminal surface of the wire stent by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film. . .

DETDESC:

DETD(24)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(26)

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) was adjusted from its collapsed. . . 8.0 mm by inserting a tapered stainless steel mandrel followed by a straight 8.0 mm diameter stainless steel mandrel. This stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. This was accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the stent. This exterior covering 61 is described by the transverse cross section of FIG. 6. A 2 mm wide seam 45. . . over these edges and

applying heat from a hand-held iron with a surface temperature of about 400.degree. C. The film-wrapped stent 65 was then placed into an oven set at 380.degree. C. for 3 minutes, after which it was removed and allowed to cool. The film appeared to be well adhered to the exterior surface of the stent. The wall thickness of the film covering was about 0.01 mm. The enlarged stent was then collapsed by the following process.

DETDESC:

DETD(27)

A series of 20 cm long 6-0 sutures were tied individually to each of the closed metal stent openings adjacent to one end of a stent. The film-covered stent was provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping was intended as a dry lubricant. As described by FIG. 7 which omits the exterior film covering for clarity, the enlarged stent 71 was then pulled by these sutures 77 through a tapered die 75 of round cross section and 2.5 cm. . . . bore at its entrance 78 and a 4.5 mm diameter bore at its exit 79. The result was that the stent was collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous expanded PTFE film aided in making it possible to pull the stent through the die. This temporary covering was removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an appropriately sized, smaller diameter exit bore would result in collapsing the stent to its original collapsed diameter. The film-covered stent was again enlarged to a diameter of 8 mm using a balloon catheter followed by a tapered stainless steel mandrel.. . . The covering of porous expanded PTFE film appeared to be fully intact after the collapsing and enlarging of the film-covered stent.

DETDESC:

DETD(28)

Stent coverings may be affixed to a stent surface by variations on this method. For example, a tubular sleeve may be made from a film of porous expanded PTFE and inverted back into itself and fitted over the inner and outer surfaces of a stent as shown by FIG. 8. The inner 83 and outer 85 portions of the tubular sleeve 81 may be thermally adhered to each other through the openings in the stent wall, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends 87 of the tube together.

DETDESC:

DETD(30)

A . . . single layer, approximate 1 mm overlap covering of porous expanded PTFE film by helically wrapping the wire with a narrow tape cut from a sheet of porous expanded PTFE film. The tape used was 6 mm wide, 0.01 mm thick, 0.3 g/cc density, and had uniaxially-oriented fibrils of about 50 micron fibril length. This tape-covered wire was then heated by pulling the wire through the 0.14 mm diameter orifice of a 2.5 cm long die heated to 400.degree. C., at a rate of 1.5 meters per minute, thereby adhering the overlapped edges of the tape together and thereby adhering the tape to the wire. This wire was then cut into shorter lengths and spooled onto 16 bobbins. These bobbins were used. . .

DETDESC:

DETD(31)

A . . . a braided covering of the above wire was applied at a density of about 16 picks/cm. An additional covering of tape cut from a sheet of porous expanded PTFE film was then helically wrapped over the surface of the wire-braided PTFE mandrel. The tape used for this helical wrapping was of 0.01 mm thickness, 0.3 g/cc density, about 50 micron fibril length and 12. . . C. for four minutes, after which it was removed and allowed to cool. As shown by FIG. 9, the wire-braided stent 91 with the exterior covering of porous expanded PTFE tape was then removed from the non-porous PTFE mandrel 93 by folding the ends 95 of the braided wires back on. . . the braided assembly from the mandrel resulted in the helical wrapping of film being located on the lumen of the stent. This construction offered good self-expanding characteristics in that when longitudinal tension was placed on the stent, the length of the stent increased and the diameter decreased. Upon release of tension, the stent immediately recovered its previous shorter length and larger diameter. This film-covered stent is therefore expected to be useful as a self-expanding stent.

CLAIMS:

CLMS(1)

We claim:

1. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) a tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular diametrically adjustable stent, said tubular covering being less than about 0.10 mm thick, and said tubular cover having an exterior surface, a luminal. . .

CLAIMS:

CLMS(2)

2. A tubular intraluminal graft according to claim 1 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the exterior surface of the tubular diametrically adjustable stent by an adhesive.

CLAIMS:

CLMS(3)

3. A tubular intraluminal graft according to claim 2 wherein the adhesive is a thermoplastic adhesive.

CLAIMS:

CLMS(4)

4. A tubular intraluminal graft according to claim 3 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer adhesive.

CLAIMS:

CLMS(5)

5. A tubular intraluminal graft according to claim 4 wherein the thermoplastic fluoropolymer adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(6)

6. A tubular intraluminal graft according to claim 1 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are substantially parallel to each other, said uniaxially-oriented fibrils being oriented circumferentially with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(7)

7. A tubular intraluminal graft according to claim 1 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are substantially parallel to each other, said uniaxially-oriented fibrils being oriented lengthwise with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(8)

8. A tubular intraluminal graft according to claim 1 wherein the porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by fibrils which are oriented. . . substantially perpendicular directions, said two substantially perpendicular directions being oriented circumferentially and longitudinally with respect to the tubular diametrically adjustable stent.

CLAIMS:

CLMS(9)

9. A tubular intraluminal graft according to claim 1 wherein the tubular diametrically adjustable stent is a Nitinol stent.

CLAIMS:

CLMS(10)

10. A tubular intraluminal graft according to claim 1 wherein the stent is a balloon-expandable stent.

CLAIMS:

CLMS(11)

11. A tubular intraluminal graft according to claim 1 wherein the stent is a self-expanding stent of braided wire.

CLAIMS:

CLMS(12)

12. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) affixing a tubular covering to the exterior surface of the tubular, diametrically adjustable stent, said covering being less than 0.10 mm thick and said tubular covering having an exterior surface, a luminal surface and. . .

CLAIMS:

CLMS(15)

15. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall, said tubular, diametrically adjustable stent having a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter, wherein said tubular, diametrically adjustable stent has been diametrically adjusted to the enlarged diameter;
b) affixing a tubular covering to the tubular, diametrically adjustable stent; and
c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter
wherein the tubular covering is affixed to the exterior surface of the tubular, diametrically adjustable stent.

US PAT NO: 5,797,933 [IMAGE AVAILABLE] L1: 11 of 37

SUMMARY:

BSUM(4)

Anastomosis . . . between them. Vascular surgery often involves creating an anastomosis between blood vessels or between a blood vessel and a vascular graft to create or restore a blood flow path to essential tissues. Coronary artery bypass graft surgery (CABG) is a surgical procedure to restore blood flow to ischemic heart muscle whose blood supply has been compromised. . . using an artificial conduit, such as one made of Dacron or Goretex tubing, and connecting this conduit as a bypass graft from a viable artery, such as the aorta, to the coronary artery downstream of the blockage or narrowing. A graft with both the proximal and distal ends of the graft detached is known as a "free graft". A second method involves rerouting a less essential artery, such as the internal mammary artery, from its native location so that it may be connected to the coronary artery downstream of the blockage. The proximal end of the graft vessel remains attached in its native position. This type of graft is known as a "pedicled graft". In the first case, the bypass graft must be attached to the native arteries by an end-to-side anastomosis at both the proximal and distal ends of the graft. In the second technique at least one end-to-side anastomosis must be made at the distal end of the artery used for the bypass. In the description below we will refer to the anastomoses on a free graft as the proximal anastomosis and the distal anastomosis. A proximal anastomosis is an anastomosis on the end of the graft vessel connected to a source of blood (e.g. the aorta) and a distal anastomosis is an anastomosis on the end of the graft vessel connected to the destination of the blood flowing through it (e.g. a coronary artery). The anastomoses will also sometimes. . . in which the anastomoses are performed regardless of whether the anastomosis is on the proximal or distal end of the graft.

SUMMARY:

BSUM(8)

In . . . CABG surgery, it would be desirable to provide a rapid means for making a reliable end-to-side anastomosis between a bypass graft or artery and the aorta or the native vessels of the heart. A first approach to expediting and improving anastomosis. . .

SUMMARY:

BSUM(9)

At . . . (U.S. Pat. No. 4,350,160), was used to create an end-to-end anastomosis between the internal mammary artery (IMA) or a vein graft and one of the coronary arteries, primarily the left anterior descending coronary artery (LAD). Because the device could only perform. . . artery is only partially occluded and is not at all applicable to making the proximal side-to-end anastomosis between a bypass graft and the aorta.

SUMMARY:

BSUM(10)

One . . . manual manipulation of the staple, using hand operated tools to individually deform the distal tines of the staple after the graft has been attached and before it is inserted into the opening made in the aortic wall. One of the more difficult maneuvers in applying the Kaster staple involves carefully everting the graft vessel over the sharpened ends of the staple legs, then piercing the everted edge of the vessel with the staple legs. Experimental attempts to apply this technique have proven to be very problematic because of difficulty in manipulating the graft vessel and the potential for damage to the graft vessel wall. For speed, reliability and convenience, it is preferable to avoid the need for complex maneuvers while performing the. . . opening. Another disadvantage of the Kaster device is that the distal tines of the staple pierce the wall of the graft vessel at the point where it is everted over the staple. Piercing the wall of the graft vessel potentially invites leaking of the anastomosis and may compromise the structural integrity of the graft vessel wall, serving as a locus for a dissection or even a tear which could lead to catastrophic failure. Because. . . critical to avoid the potential for thrombosis. There is also the potential that exposure of the medial layers of the graft vessel where the staple pierces the wall could be a site for the onset of intimal hyperplasia, which would compromise the long-term patency of the graft. Because of these potential drawbacks, it is desirable to make the attachment to the graft vessel as atraumatic to the vessel wall as possible and to eliminate as much as possible the exposure of any. . . foreign materials or any vessel layers other than a smooth uninterrupted intimal layer within the anastomosis site or within the graft vessel lumen.

SUMMARY:

BSUM(11)

A . . . to Kaster for an Anastomotic Fitting. This device is a four-part anastomotic fitting having a tubular member over which the graft vessel is everted, a ring flange which engages the aortic wall from within the aortic lumen, and a fixation ring. . . a flanged distal end that fastens to the aortic wall with an attachment ring, and a proximal end with a graft fixation collar for attaching to the graft vessel. These devices have a number of drawbacks that the present invention seeks to overcome.

SUMMARY:

BSUM(12)

Firstly, . . . be exposed to the blood flow path be covered with vascular tissue, either from the target vessel or from the graft vessel, so that a smooth, continuous, hemocompatible endothelial layer will be presented to the bloodstream.

SUMMARY:

BSUM(13)

The anastomotic fitting described by Kaster in the '819 patent also has the potential drawback that the spikes that hold the graft vessel onto the anastomotic fitting are very close to the blood flow path, potentially causing trauma to the blood vessel. . . mechanical integrity of the vessels. Consequently, it is desirable to provide an anastomosis fitting that is as atraumatic to the graft vessel as possible. Any sharp features such as attachment spikes should be placed as far away from the blood flow. . .

SUMMARY:

BSUM(17)

A . . . the coronary shunt is to use a tourniquet extending around the middle of the shunt. The tourniquet extends through the graft and is pulled through the graft when the anastomosis is complete. A

problem with this method of removing the shunt is that the graft may be damaged by the shunt when the shunt is pulled through the graft. Another problem with this method is that it cannot be used when the internal mammary artery is used since the proximal end of the graft is not cut open for removing the shunt.

SUMMARY:

BSUM(18)

Another method of removing the shunt is to simply pull the shunt through an opening between the graft and the coronary artery before the anastomosis is complete. A problem with this method of removing the shunt is that. . .

SUMMARY:

BSUM(20)

In . . . their use in performing an end-to-side vascular anastomosis. The system is especially useful for performing an anastomosis between a vascular graft and the wall of the ascending aorta in CABG surgery, particularly in port-access CABG surgery. One desirable attribute of the anastomosis system is that the system should be as atraumatic as possible to the graft vessel in creating the anastomosis. Another desirable attribute of the anastomosis system is that the anastomosis device should minimize the. . . ring-shaped body having a proximal end and a distal end. An orifice or internal lumen in the body allows the graft vessel to pass through the device from the proximal end to the distal end. The body of the device has an attachment means at the distal end for attachment to the graft vessel, generally by everting the graft vessel over the attachment means. Means are provided for attaching the device and the graft vessel to the wall of the target vessel. Different embodiments of the anastomosis device are presented which vary in the form of the means used for attaching to the graft vessel and the target vessel.

SUMMARY:

BSUM(21)

A . . . part of an overall anastomosis stapling system and method designed to efficiently and reliably perform an end-to-side anastomosis between a graft vessel and the wall of a target vessel. The anastomosis staple device forms an atraumatic attachment to the end of the graft vessel so that only a smooth uninterrupted layer of intimal cells is exposed at the anastomosis site or within the graft vessel lumen. The anastomosis staple device creates a firm, reliable attachment between the graft vessel and the target vessel wall, with a tailored amount of tissue compression applied at the anastomosis site to form a leak-proof joint between the graft vessel and the target vessel wall. The anastomosis stapling system is designed to combine the various functions of graft vessel preparation, target vessel preparation, vessel approximation and anastomosis stapling into an integrated system of instruments so that the anastomosis. . .

SUMMARY:

BSUM(22)

In . . . anchor member forms the attachment with the target vessel wall. The coupling member separately forms the attachment with the bypass graft vessel. The complete anastomosis is created when the coupling member, with the graft vessel attached, is inserted into the anchor member. In a second preferred configuration of the invention, the anastomosis staple device. . . coupling member into a single member. A one-piece anastomosis staple device attaches to both the target vessel wall and the graft vessel to form a complete end-to-side anastomosis. In all embodiments of the anastomosis staple device, certain desirable aspects are maintained, specifically the atraumatic attachment of the device to the graft vessel and the rapid, reliable formation of the anastomosis, as well as the adaptability of the staple device to port-access. . .

SUMMARY:

BSUM(23)

A second aspect of the present invention takes the form of an anastomotic fitting for attaching the end of a graft vessel to an opening formed in the side wall of a target vessel. The anastomotic fitting has an inner flange which provides an atraumatic attachment for the everted end of a graft vessel. The inner flange is configured so that, wherever possible, a smooth, continuous, uninterrupted layer of intimal tissue lines the graft vessel, the target vessel and the anastomotic site, with as little foreign material as possible exposed to the blood flow. . . compression applied by the inner and outer flanges

grips the target vessel wall and creates a leak-proof seal between the graft vessel and the target vessel. Optionally, attachment spikes on the surfaces of either the inner or the outer flange provide additional grip on the graft vessel and/or the target vessel. The attachment spikes are isolated from the blood flow lumens of the graft vessel and the target vessel so that they do not compromise the anastomotic seal or the structural integrity of the. . .

SUMMARY:

BSUM(24)

In . . . a) a tubular inner sleeve, which has an internal lumen of sufficient size to accommodate the external diameter of the graft vessel and an inner flange which is attached at the distal end of the inner sleeve, and b) an outer. . .

SUMMARY:

BSUM(25)

The anastomosis procedure is performed by passing the end of the graft vessel through the inner lumen of the inner sleeve until the end of the vessel extends a short distance from the distal end of the sleeve. The end of the graft vessel is then everted over the inner flange of the fitting to form an atraumatic attachment. A loop of suture or spikes on the outside of the inner sleeve or flange may be added to help retain the graft vessel in its everted position. The inner flange and the everted end of the graft vessel are then passed through an opening that has previously been made in the wall of the target vessel with. . . vessel wall around the opening helps to create an anastomotic seal by contracting around the inner sleeve and the everted graft vessel wall. The outer flange is then slid onto the proximal end of the inner sleeve. If the anastomosis being performed is the first anastomosis on a free graft, such as a saphenous vein graft, then the outer flange can be slid over the graft vessel from the free end. If the other end of the graft vessel is not free, such as when performing the second anastomosis of a free graft or a distal anastomosis on a pedicled graft like the IMA, then the outer flange should be back loaded onto the graft vessel or preloaded onto the proximal end of the inner sleeve before the end of the graft vessel is attached to the inner flange of the fitting. The outer flange is slid down the inner sleeve until. . .

SUMMARY:

BSUM(26)

A second representative embodiment of the anastomotic fitting has an expanding inner flange which facilitates the atraumatic attachment of the graft vessel to the fitting and makes it easier to pass the inner flange and the everted graft vessel through the opening in the target vessel wall. The graft vessel is passed through an internal lumen of an inner sleeve which has the expandable inner flange attached at its distal end. The end of the graft vessel is everted over the unexpanded inner flange. The inner flange and the everted end of the graft vessel are passed through the opening in the target vessel wall. Once the inner flange of the fitting is in. . .

SUMMARY:

BSUM(27)

Different . . . inward toward the center of the sleeve. A second inner sleeve is slidably received within the slotted inner sleeve. The graft vessel is inserted through the internal lumen of both sleeves and everted over the collapsed fingers of the flange. The. . .

SUMMARY:

BSUM(28)

A . . . tabs engage the distal ends of the fingers of the slotted inner sleeve. The anastomosis is performed by passing the graft vessel through the internal lumen of the fitting and everting it over the fingers. If desired, a loop of suture. . . be used to hold the everted vessel in place. The fingers of the fitting and the everted end of the graft vessel are inserted through an opening in the target vessel wall. When the tubular forming tool is slid proximally with. . .

SUMMARY:

BSUM(29)

A . . . integrally attached to a fixed inner flange and to a deformable outer flange. The anastomosis is performed by passing the graft vessel through the internal lumen of the inner sleeve and

everting it over the inner flange. The inner flange and the everted end of the graft vessel are inserted through an opening in the wall of the target vessel. Then, the outer flange is deformed against. . .

SUMMARY:

BSUM(31)

A . . . previous Kolesov stapling device by allowing a stapled end-to-side anastomosis. This device, however, requires many delicate manual manipulations of the graft vessel and the staple while performing the anastomosis. This device therefore does not take full advantage of the time saving. . .

SUMMARY:

BSUM(32)

The . . . around the anastomotic interface to eliminate potential leaks between the stapled attachments. The ring or flange also serves as a stent or support for the anastomosis site to prevent acute or long-term closure of the anastomosis. Inasmuch as possible the bulk. . . is kept on the exterior of the anastomosis so as to eliminate exposed foreign material in the bloodstream of the graft vessel or the target vessel. In most cases, only the narrow staple legs penetrate the anastomosis site, so that an. . . suture exposed in a standard sutured anastomosis. The attachment technique for the anastomosis device eliminates the need to evert the graft vessel over a complex, irregular or sharp object such as the sharpened ends of the staple legs. Instead, a smooth ring or flange surface is provided for everting the graft vessel without damage or undue complication. The staple legs are separate or recessed within the flange to avoid potential damage to the graft vessel while attaching it to the device.

SUMMARY:

BSUM(33)

In . . . aspect, the present invention takes the form of an anastomosis device which has a ring or flange to which the graft vessel attaches, typically by everting the graft vessel over the distal end of the ring. The ring or flange resides on the exterior of the graft vessel so that it does not contact the blood flow path. A plurality of staple-like members attach the ring and the everted end of the graft vessel to the wall of the target vessel, which may be the aorta, a coronary artery or other vessel. An. . . target vessel wall with an aortic punch or similar instrument to allow the target vessel lumen to communicate with the graft vessel lumen. The opening in the target vessel wall can be made before or after the device has been attached,. . . on the application technique employed. In most of the examples disclosed, the staple members pierce the everted wall of the graft vessel and the wall of the target vessel to hold the two vessels together. Alternatively, the staple members may enter. . .

SUMMARY:

BSUM(34)

Various . . . deformable staple members for attaching the flange. A specially adapted staple applying device which operates through the lumen of the graft vessel is used to deform the staples to complete the anastomosis. A second embodiment includes a ring-like fastening flange with. . .

SUMMARY:

BSUM(35)

Catheter . . . coronary artery during the anastomosis procedure. A third catheter device is configured to be delivered through the lumen of the graft vessel for isolating a portion of a coronary artery during the anastomosis procedure.

DRAWING DESC:

DRWD(7)

FIGS. 6A is a perspective view of the graft insertion tool of the anastomosis staple applier system of FIG. 2 prepared for insertion of the bypass graft with the coupling member of the two-piece anastomosis staple device. FIGS. 6B-6C are side cross section and perspective views, respectively, of the distal end of the graft insertion tool of FIG. 6A.

DRAWING DESC:

DRWD(8)

FIGS. 7A-7C are perspective, bottom end, and side cross section views, respectively, showing a variation of the graft insertion tool prepared for creating a second anastomosis of the bypass graft using the two-piece anastomosis staple device of FIG. 1.

DRAWING DESC:

DRWD(15)

FIG. . . . end of the staple applying tool of FIG. 13 holding the one-piece anastomosis staple device of FIG. 9 with a graft vessel attached thereto.

DETDESC:

DETD(2)

The . . . describes the invention in relation to a proximal anastomosis during CABG surgery for joining the proximal end of the bypass graft to the aortic wall. This example is given by way of illustration only and is in no way meant to. . . staple device and anastomosis stapling system of the present invention are readily adaptable for end-to-side connections of distal anastomoses (i.e. graft to coronary artery anastomoses) during CABG surgery, as well as for use on other blood vessels and other tubular organs. . .

DETDESC:

DETD(3)

FIG. . . . the wall of a target vessel such as the aorta. The coupling member 102 forms the attachment to the bypass graft vessel. When the coupling member is joined to the anchor member, as shown by the dotted lines 103, it forms. . .

DETDESC:

DETD(6)

The . . . 101 rather than a plane. This would be especially important when there is closer parity between the diameter of the graft vessel and the diameter of the target vessel, such as when performing a distal anastomosis between a venous or arterial graft and a coronary artery, because a planar arrangement of the attachment legs 105 would not approximate the curvature of the. . . attachment legs 105 may be angled with respect to the ring-shaped frame 104 to permit an angled takeoff of the graft vessel from the target vessel.

DETDESC:

DETD(8)

This . . . to create a closer approximation of the tissues being joined. This type of distortion may be counterproductive in attaching a graft vessel to the aortic wall because the wall may be too stiff to distort in this manner and the distortion. . .

DETDESC:

DETD(9)

The . . . target vessel wall around the anastomosis helps to create and maintain an anastomotic seal between the target vessel and the graft vessel in the completed anastomosis. This is especially important when blood pressure is restored in the target vessel which will. . .

DETDESC:

DETD(10)

The . . . a passage 114 through it. The distal end of the coupling 102 has an atraumatic edge 115 over which the graft vessel will be everted in forming the anastomosis. The atraumatic edge 115 is important to avoid piercing or damaging the vessel wall in the vicinity of the anastomosis which occurs with some prior art devices. Atraumatic attachment of the graft vessel to the coupling member helps to assure a reliable anastomotic seal between the graft vessel and the target vessel and reduces the likelihood of mechanical failure of the graft vessel wall due to punctures or tears in the wall. The exterior of the coupling member 102 is sized to. . . ring-shaped frame 104 of the anchor member with enough space between them to accommodate one wall thickness of the bypass graft. The coupling member 102 is preferably made of stainless steel, a titanium alloy or plastic with a wall thickness of. . . 116 which serve a dual purpose. The exterior surface features 116 serve to hold the everted end of the bypass graft onto

the coupling member 102, as well as to interlock the coupling member 102 with the anchor member 101 to. . . features of the anastomosis staple device 100, these potentially traumatic features are located away from the everted edge of the graft vessel and outside of the lumens of the graft vessel and target vessel that will serve as the conduit of the bypass so as not to compromise the integrity. . .

DETDESC:

DETD(11)

In the embodiment illustrated, the coupling member 102 is shown with bump-shaped exterior surface features 117 that hold the everted graft vessel onto the coupling member 102 and interlock with a series of circumferential ridges 116 within the anchor member 101.. . . coupling member 102 and the anchor member 101 to allow for different wall thicknesses of the target vessel and the graft vessel used in the anastomosis. The axial position of the coupling member 102 with respect to the anchor member 101. . .

DETDESC:

DETD(12)

The . . . staple 100 consists of three separate, but interacting, mechanisms: a stapling mechanism 119, a vessel punch mechanism 120, and a graft insertion tool 121, 122. Together with the anchor member 101 and the coupling member 102, they comprise a complete system. . . member 101 of the anastomosis staple 100, prepared for the first stage of the anastomosis procedure. The third mechanism, the graft insertion tool, is shown in two different embodiments 121, 122 in FIGS. 6A-6C and FIGS. 7A-7C, respectively.

DETDESC:

DETD(13)

The . . . inner tube 124 has an internal lumen 128 of sufficient size to accommodate the vessel punch mechanism 120 and the graft insertion tool 121, alternately. The proximal end of the inner tube 124 has a pair of opposing slots 129 on. . . with a corresponding pair of lugs 130, 134 on the exterior of the vessel punch mechanism 120 and on the graft insertion tool 121.

DETDESC:

DETD(17)

The . . . of the stapler inner tube 124. Likewise, in the latter stages of the procedure, the T-shaped handle 133 of the graft insertion tool 121 can also serve as a handle for the inner tube 124 of the stapling mechanism 119 because the lugs 134 of the graft insertion tool 121 engage the inner slots 129 of the stapler inner tube 124 in a similar fashion. Alternatively, the. . . rotated with respect to one another to operate the stapling mechanism when neither the aortic punch mechanism 120 nor the graft insertion tool 121 is inserted into the stapling mechanism 119.

DETDESC:

DETD(18)

A first embodiment of the graft insertion tool 121 and its relationship to the coupling member 102 of the anastomosis staple 100 are shown in detail in FIGS. 6A-6C. This embodiment of the graft insertion tool 121 may be used when the anastomosis staple 100 is used to form the first anastomosis of the bypass procedure no matter whether the first anastomosis is the proximal or the distal anastomosis of the graft. To prepare the bypass graft for creating the anastomosis, the coupling member 102 is first loaded onto the distal end of the graft insertion tool 121. A shoulder 147 on the graft insertion tool 121 holds the coupling member 102 in the correct position, and a tight interference fit or a spring action prevents it from inadvertently falling off. The graft vessel 148 is then loaded into the internal lumen 149 of the graft insertion tool 121. This can be done by tying a suture around the graft vessel on the end opposite to the end that will be anastomosed, passing the suture through the internal lumen 149 of the graft insertion tool 121, then drawing the graft vessel 148 into the lumen until the end 192 of the graft vessel 148 to be anastomosed extends a short distance from the distal end of the graft insertion tool 121. Alternatively, a special tool, such as a narrow pair of endoscopic forceps or a nerve hook, may be used for grasping the graft vessel 148 and drawing it through the graft insertion tool 121. At this point, the end 192 of the graft vessel 148 to be anastomosed is everted over the end of the graft insertion tool 121 and the coupling member 102, as shown in FIGS. 6A-6C. The external surface features 116 of the coupling member 102 serve to hold the

graft vessel onto the exterior of the coupling member 102 in the everted position. The external surface features 116 of the coupling member may at least partially penetrate the wall of the graft vessel 148 to provide greater holding force.

DETDESC:

DETD(19)

With the anchor member 101 loaded onto the stapling mechanism 119 and the graft vessel 148 prepared by everting and attaching it to the coupling member 102 as described above, the device is ready. . .

DETDESC:

DETD(20)

The graft vessel insertion tool 121 with the prepared graft vessel 148 and coupling member 102 in place is inserted into the inner lumen 128 of the stapling mechanism 119. . . frame 101. The coupling member 102 should be pressed into the ring-shaped frame 104 until the everted end of the graft vessel 148 bears against the exterior surface of the target vessel wall 150, creating a fluid tight seal at the anastomosis site. Alternatively, the coupling member 102, with the everted end of the graft vessel 148 attached, can be made to extend into the opening 152 in the target vessel wall 150 with the target vessel wall 150 creating a radial compression around the graft vessel 148 and the coupling member 102. The stapling mechanism 119 can now be disengaged from the from the anchor. . . member 101 by turning the handle 126 of the outer tube 125 with respect to the T-handle 133 of the graft insertion tool 121 until the staple driver is withdrawn from the attachment legs 105. Then the inner tube 124 of the stapling device can be turned counterclockwise by turning the T-shaped handle 133 of the graft insertion tool 121 to disengage the gripping fingers 144 of the staple retainer 123 from the attachment legs 105 of. . .

DETDESC:

DETD(21)

It . . . aortic punch or similar instrument, and then the anchor member of the staple could be attached. In this instance, the graft vessel could be attached to the anchor member either before or after the anchor member is attached to the target. . .

DETDESC:

DETD(22)

FIG. 7A shows a perspective drawing of a second embodiment of the graft insertion tool 122 for use in performing the second anastomosis on a graft vessel, one end of which has already been anastomosed, or for other situations when both ends of the graft vessel are not available, such as when making the distal anastomosis on an internal mammary artery bypass graft. This embodiment of the graft insertion tool 122 is made with a two-part, hinged holder 154 for the coupling member of the anastomosis staple device so that the holder 154 can be removed from around the graft vessel 148 after both ends of the graft have been anastomosed. The holder 154 is attached to the distal end of a tubular member 155 which is attached. . .

DETDESC:

DETD(23)

To prepare the graft vessel 148 for the anastomosis, the coupling member 102 is first placed onto the holder 154 and the end of the graft vessel 148 to be anastomosed is passed through the lumen 162 of the holder 154 and the coupling member 102 from the proximal to the distal end. The end of the graft vessel 148 is then everted back over the coupling member 102, as shown in FIG. 7C. The external surface features. . . counterclockwise relative to the handle 126 on the vessel punch mechanism 120 until the anchor member 101 is released. The graft insertion tool 122 with the prepared graft vessel 148 is now positioned at the anastomosis site and the U-shaped yoke 158 is used to grip the anchor member 101, retained by the flange 159 on its proximal end. With the graft vessel 148 and the coupling member 102 aligned with the anchor member 101 as shown, the handle grip 156 and. . . are squeezed together to press the coupling member 102 into the anchor member 101 until the everted end of the graft vessel 148 is pressed against the outer surface of the target vessel 150 creating a leak-proof anastomosis. The holder 154. . . the handle grip 154. The hinged holder 154 opens when it is withdrawn from the coupling member 102, releasing the graft vessel 148 from the lumen 162 of the holder 154. The U-shaped yoke 158 can now be slid sideways off. . .

DETDESC:

DETD(25)

FIG. . . . has a tubular body member 164 which has an inner lumen 165 sized to accommodate the exterior diameter of the graft vessel 148. Means for attaching the graft vessel 148 are provided at the distal end of the tubular body member 164 or on the outside of the tubular member 164. In the preferred embodiment, the means for attaching the graft vessel 148 to the anastomosis staple 163 is a tubular distal extension 166 of the tubular body over which the graft vessel 148 is everted. The tubular extension 166 may include a flange 167 to secure the attachment of the everted graft vessel 148 to the tubular extension 166. This flange 167 may also engage the inner surface of the target vessel 150 to help retain the graft 148 in place.

DETDESC:

DETD(30)

The . . . member 164. In the embodiment of FIG. 12, the staple legs 168 are configured to pierce the wall of the graft vessel 148 just proximal to the flange 167 on the distal end 166 of the tubular body member 164, adding. . .

DETDESC:

DETD(31)

FIG. . . . 180. The inner tube 181 has an inner lumen 182 of sufficient diameter to accommodate the outer diameter of the graft vessel 148 that will be used for the anastomosis. The staple applying tool 179 has a main body 183 which. . .

DETDESC:

DETD(32)

A . . . The tubular body 164 has a distal tubular extension 166 with a flange 167 for eversion and attachment of the graft vessel 148. There is also a proximal tubular extension 169 which has a pair of tabs 170 for grasping the. . .

DETDESC:

DETD(34)

To prepare the graft vessel 148 for anastomosis, an anastomosis staple 163 is attached to the distal end of the staple applying tool 179 as just described, then, using a suture or an elongated grasping tool, the graft vessel 148 is drawn into the inner lumen 182 of the tool until the end 192 of the graft vessel 148 to be anastomosed extends a short distance from the distal end of the tool. At this point, the end 192 of the graft vessel 148 to be anastomosed is everted over the distal tubular extension 166 and the flange 167 as shown in FIG. 14. A suture can be tied around the everted end 192 of the graft vessel 148 proximal to the flange 167 to retain the graft vessel 148 on the staple 163, if desired.

DETDESC:

DETD(35)

Thus . . . of the staple 163 just proximal to the flange 167. The flange 167 with the everted end 192 of the graft vessel 148 is passed through the opening 152 in the target vessel 150, as shown in FIG. 10. The target. . . force where the target vessel wall 150 surrounds the distal tubular extension 166 with the everted end 192 of the graft vessel 148 which contributes to the fluid-tight seal of the anastomosis.

DETDESC:

DETD(36)

Once . . . target vessel 150, the anastomosis staple 163 is pulled back slightly so that the flange 167, covered by the everted graft vessel wall 192, is against the inner surface of the target vessel wall 150. Then, the staple 167 is actuated. . .

DETDESC:

DETD(38)

In . . . on the distal end of the tubular body member, making it easier to insert the flange 205, with the everted graft vessel 192 attached, into the opening in the target vessel 150 and to seat the flange 205 against the inner. . . degrees as the curved fourth segment 203 of the staple leg 194" penetrates the target vessel wall 150,

attaching the graft vessel 148 to the target vessel 150 to complete the anastomosis.

DETDESC:

DETD(40)

A . . . of FIG. 1. The coupling member 209, shown in FIG. 17B, has a tubular body 217 with a plurality of graft holding points 218 extending from its distal edge. If desired, the graft holding points 218 could be relocated, replaced with other gripping features, or eliminated entirely to avoid piercing the graft vessel 148 at the point of eversion. The graft holding points 218 perform one of the functions of the exterior surface features 116 of the coupling device 102 shown in FIG. 1 in that they attach the graft vessel 148 to the coupling member 209.

DETDESC:

DETD(42)

Once the anchor member 208 is attached to the target vessel 150, the vessel punch mechanism 120 is withdrawn and the graft insertion tool 121 with the graft vessel 192 everted over the distal end of the coupling member 209 is inserted into the inner lumen 128 of the stapling mechanism 119. The graft insertion tool 121 is used to press the coupling member 209 into the ring-shaped frame 210 of the anchor member 208 until the everted end 192 of the graft vessel 148 is firmly sealed against the outer surface of the target vessel wall 150 and the retaining clips 216. . . . coupling member 209. The coupling member 209 is held in the ring-shaped frame 210 by the retaining clips 216. The graft holding points 218 may be made so that they penetrate through the graft vessel wall 192 and into the target vessel wall 150, as shown in FIG. 17C, to increase the security of. . .

DETDESC:

DETD(43)

Another . . . end of the tubular extension 223 that serves as a strain relief to prevent sharp bends or kinking of the graft vessel 148 close to the anastomosis site.

DETDESC:

DETD(45)

The . . . smaller than the inside diameter of the cylindrical extension 223. The coupling member 225 is shown in FIG. 18D. The graft vessel 148 is prepared for anastomosis by passing the end of the vessel through the central opening of the toroidal. . . . 225 and everting it back 192 over the ring, as shown in the FIG. 18E. The ring 225, with the graft vessel 192 everted over it, is then collapsed or folded enough so that it can be inserted into the proximal. . . . anchor member 220. Once through the cylindrical extension 223, the toroidal ring 225 recoils to its expanded size, sealing the graft vessel wall 192 against the wall of the target vessel 150 and preventing the end of the graft vessel 192 from pulling out of the tubular extension 223. Alternatively, a cylindrical ring-shaped coupling member with locking features, similar. . .

DETDESC:

DETD(47)

The . . . locked onto the edges of the aperture 228. The first tubular coupling member 232 may be made with integrally formed graft holding points 236 which are cut and bent inward from the wall of the first tubular coupling member 232 to hold the everted graft in place. The graft may be everted over a second tubular coupling member 196, which is inserted into the first tubular coupling member 232. . .

DETDESC:

DETD(51)

Meanwhile, the graft vessel 148 is prepared by placing it through the lumen of the tubular coupling member and everting the end 192 of the graft vessel 148 over the outside of the coupling member 245. To complete the anastomosis, the coupling member 245 with the end 192 of the graft vessel 148 attached is collapsed or folded and inserted into the proximal tubular extension 244 of the anchor member 238.. . .

DETDESC:

DETD(52)

The . . . coupling member 245 extends through the opening 152 in the target vessel wall and the everted edge 192 of the graft vessel 148 seals within the opening 152, as illustrated, or against the interior surface of the target vessel 150 similarly. . .

DETDESC:

DETD(53)

Alternatively, the coupling member 245 can be shaped so that it presses the everted edge 192 of the graft vessel 148 against the exterior surface of the target vessel 150 to create a leak-proof seal similar to the embodiment. . .

DETDESC:

DETD(54)

In . . . further aspect of the invention, an anastomosis fitting is provided for rapidly and reliably creating an end-to-side anastomosis between a graft vessel and a target vessel. A first representative embodiment of an anastomotic fitting 250 according to this second aspect of. . . tubular inner sleeve 251 which has an internal lumen 252 of sufficient size to accommodate the external diameter of the graft vessel 254 and an inner flange 253 which is attached or formed at the distal end of the sleeve 251. . .

DETDESC:

DETD(55)

The . . . sleeve 251 is a tubular member with an internal lumen 252 large enough to accommodate the external diameter of the graft vessel 254, either a natural graft vessel or an artificial graft vessel. Natural saphenous vein autografts typically have an internal diameter between 3 mm and 10 mm and an external diameter. . . and 7 mm and an external diameter between 3 mm and 8 mm, with thicker, more muscular walls. Artificial prosthetic graft vessels, made of materials such as Dacron or Goretex, typically have a diameter of 3 mm to 30 mm. The. . .

DETDESC:

DETD(56)

The . . . helps to improve the hemodynamic efficiency of the anastomosis connection by improving the orifice coefficient at the entrance to the graft vessel 254. It also assures that the finished anastomosis will not protrude into the lumen 246 of the target vessel. . .

DETDESC:

DETD(57)

The . . . spikes 266 that engage and hold the wall of the target vessel 255 and/or the everted wall 259 of the graft vessel 254 when the outer flange 260 is applied. In the preferred embodiment which is intended for creating an anastomosis between a coronary artery bypass graft and the ascending aorta, the outer flange 260 has 4 to 12 spikes of 1 to 3 mm length and 0.2 to 0.5 mm diameter. Variations of this configuration may be made where appropriate for different graft vessels and target vessels.

DETDESC:

DETD(58)

The anastomosis is performed by passing the end 259 of the graft vessel 254 through the inner lumen 252 of the tubular inner sleeve 252 until the end of the vessel extends. . . the distal end of the sleeve, as shown by phantom lines 259' in FIG. 21A. The end 259 of the graft vessel 254 is then everted over the conical inner flange 253 of the fitting 250 to form an atraumatic attachment,. . . shown in FIG. 23A. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to hold it in place on the inner flange 253 and/or the tubular inner sleeve 251. The conical inner flange 253 and the everted end 259 of the graft vessel 254 are then passed through an opening 267 that has previously been made in the wall of the target. . . around the opening 267 helps to create an anastomotic seal by contracting around the inner sleeve 251 and the everted graft vessel wall 259. The outer flange 260 is then slid onto the proximal end of the inner sleeve 251. If the anastomosis being performed is the first anastomosis of a free graft, such as a saphenous vein graft, with the other end of the graft unattached, then the outer flange 260 can be slid over the graft vessel 254 from the free end. If the other end of the graft vessel 254 is not free, such as when performing a second anastomosis or a distal anastomosis on a pedicled graft like the IMA,

then the outer flange 260 should be back loaded onto the graft vessel 254 or preloaded onto the proximal end of the inner sleeve 251 before the end 259 of the graft vessel 254 is attached to the inner flange 253 of the fitting 250. The outer flange 260 is slid down. . .

DETDESC:

DETD(59)

FIGS. . . . wall 257 of the target vessel 255. This helps to assure a hemodynamically correct inflow at the entrance to the graft vessel 254. Two or more collars 274 may be provided on the tubular inner sleeve 275 to allow adjustable compression. . .

DETDESC:

DETD(61)

FIGS. . . . the anastomosis fitting. In this embodiment, the method includes applying a suture 281 to the everted end 259 of the graft vessel 254 to secure it to the inner flange 282. As best seen in the top view FIG. 23D, the everted end 259 of the graft vessel 254 has been secured to the inner flange 282 of the fitting by making a running stitch around the end of the graft vessel with a suture 281 on the back of the inner flange 282 and tying it to create a purse string that holds the end 259 of the graft vessel 254 in place.

DETDESC:

DETD(62)

A . . . employing inner 284 and outer 285 flanges has an expanding inner flange 284 which facilitates the atraumatic attachment of the graft vessel 254 to the fitting 283 and makes it easier to pass the inner flange 284 and the everted graft vessel 259 through the opening 267 in the target vessel wall 255. Two variations of such an expanding inner flange are shown in FIGS. 24A-24D and FIGS. 25A-25H. The graft vessel 254 is passed through an internal lumen 287 of an inner sleeve 286 which has the expandable inner flange 284 attached at its distal end. The end 259 of the graft vessel 254 is everted over the unexpanded inner flange 284'. The inner flange 284' and the everted end 259 of the graft vessel 254 are passed through the opening 267 in the target vessel wall 255. Once the inner flange 284' of. . .

DETDESC:

DETD(63)

In . . . together to form a smaller diameter flange 284' with a passage 287' through the center large enough for a collapsed graft vessel 254 to fit through. A tubular former 290 is slidably received within the slotted inner sleeve 286 and has an axial lumen 291 large enough to receive the graft vessel 254. The tubular former 290 initially resides in a proximal position, as shown in FIG. 24A. The tubular former. . . outer flange 285 can be provided as a separate component which is attached to the inner sleeve 286 after the graft vessel 254 has been attached or at the end of the anastomosis procedure.

DETDESC:

DETD(64)

In operation, the graft vessel 254 is inserted through the axial lumen 291 of the tubular former 290 and through the internal lumen 287. . . through the central opening 287' between the collapsed sectors 289' of the inner flange 284'. The end 259 of the graft vessel 254 is everted over the collapsed sectors 289' of the flange 284'. The collapsed flange 282' and the everted end 259 of the graft vessel 254 are inserted through the opening 267 in the target vessel 255. Then, the tubular former 290 is slid. . .

DETDESC:

DETD(66)

The anastomosis is performed by passing the graft vessel 254 through the internal lumen of the forming tool 303 within the slotted inner sleeve 295 and everting it. . . the everted vessel 259 in place. The fingers 296 of the fitting 294 and the everted end 259 of the graft vessel 254 are inserted through an opening 267 in the target vessel wall 255. When the tubular forming tool 303. . .

DETDESC:

DETD(69)

The . . . 306 has a tubular main body 307 having an internal lumen

303 sized to accommodate the external diameter of the graft vessel 254. A fixed inner flange 309 is attached to the distal end of the tubular body 307. On the. . .

DETDESC:

DETD(71)

The . . . anastomosis by attaching the fitting 306 to the gripper 316 on the distal end of the anvil 314. Then, the graft vessel 254 is passed through the inner lumen 319 of the anvil 314 until the end 259 to be anastomosed extends a short distance from the distal end of the fitting 306. The end of the graft vessel 259 is everted over the inner flange 309 of the fitting to form an atraumatic attachment between the two.. . . access port made through one of the intercostal spaces. The inner flange 309 and the everted end 259 of the graft vessel 254 are inserted through an opening 267 that has been made in the wall of the target vessel 255.. . .

DETDESC:

DETD(72)

The . . . this embodiment, the inner flange 322 is slightly conical in order to provide a more hemodynamically efficient inlet to the graft vessel 254 at the anastomosis. In addition, a plurality of attachment spikes 323 preferably 6 to 8 spikes, have been. . . preferred configuration, the anastomotic fitting 320 is fully deployed, the spikes 323 penetrate through the everted wall 259 of the graft vessel 254 and into the wall of the target vessel 255 to create a more secure attachment for the anastomosis.. . .

DETDESC:

DETD(73)

The . . . 325 has a tubular main body 327 with an internal lumen 328 sized to accommodate the external diameter of the graft vessel 254. The walls of the tubular body 327 have a pair of L-shaped slots 329 that are open at. . .

DETDESC:

DETD(75)

The . . . is prepared for performing the anastomosis by attaching the anastomotic fitting 325 to the inner tubular member 336. Then, the graft vessel 154 is passed through the inner lumen 340 of the inner tubular member 336 until the end 159 to be anastomosed extends a short distance from the distal end of the fitting 325. The end 159 of the graft vessel 154 is everted over the inner flange 330 of the fitting 325 to form an atraumatic attachment, as shown. . . access port made through one of the intercostal spaces. The inner flange 330 and the everted end 159 of the graft vessel 154 are inserted through an opening 267 that has been made in the wall of the target vessel 225,. . .

DETDESC:

DETD(76)

A . . . veins are no longer as resilient as they once were, where it may be difficult to stretch the saphenous vein graft enough to evert it over a large inner flange. This is also true of many artificial graft materials that will not stretch at all to evert them over a large flange. The anastomosis fitting 340 of FIG.. . .

DETDESC:

DETD(77)

In . . . the application device 351. Next, the tubular body 341 is threaded onto the distal end of the holder 352. The graft vessel 254 is passed through the internal lumen 353 of the application instrument 351 and the distal end 259 of the graft vessel 254 is everted over the small primary inner flange 342 of the anastomosis fitting 340. The secondary inner flange. . . proximal face of the inner flange 342, as shown in FIG. 29A. The primary inner flange 342, with the everted graft vessel 259 attached, and the secondary inner flange washer 344 are inserted through an opening 267 that has been made. . .

DETDESC:

DETD(78)

A . . . the secondary inner flange washer 344 adds to the security of the anastomosis attachment, while it does not require the graft

vessel 254 to be stretched to fit over a large inner flange. Only a very small amount of foreign material. . . likelihood of complications. Because the secondary inner flange 344 washer only contacts the primary inner flange 342 and the everted graft vessel wall 259 at four small points, it will not interfere with the intima-to-intima approximation of the graft vessel 259 and the target vessel 255 which is preferred in order to promote endothelialization of the anastomosis site.

DETDESC:

DETD(79)

FIGS. . . . its distal end, with an outer flange 358. The deformable attachment legs 357 have an initial position 357 allowing the graft vessel 254 to be easily everted over and penetrated by the attachment legs 357. The attachment legs 357 are subsequently. . . cobalt. The tubular member 356 has an internal lumen 359 of sufficient size to accommodate the external diameter of the graft vessel 254. The tubular member 356 is made with a plurality of attachment legs 357 extending axially from its distal. . . legs 357. Other exemplary embodiments may have from three to twelve attachment legs 357 depending on the sizes of the graft vessel 254 and target vessel 255 to be joined. The attachment legs 357 preferably have a width of approximately 0.5-2.0. . . anastomosis system. The distal ends 361 of the attachment legs 357 are sharpened to easily penetrate the walls of the graft vessel 254 and target vessel 255. The exterior surface of the tubular member 256 may be made with a groove. . .

DETDESC:

DETD(82)

In . . . the end-to-side anastomosis procedure is performed using the anastomosis fitting 355 by first preparing the free end 259 of the graft vessel 254 for attachment. If the anastomosis being performed is a second anastomosis or is being performed on the free end of a pedicled graft, the outer flange 358 must first be backloaded onto the graft vessel 254 with the distal surface 367 facing the end 259 of the vessel to be attached. If the anastomosis is being performed as the first anastomosis on a free graft, the outer flange 358 can be backloaded onto the graft vessel 254 at this time or it can be passed over graft vessel 254 from the far end at a later point in the procedure, whichever is preferable. Next, the free end 259 of the graft vessel 254 is passed through the internal lumen 359 of the inner tubular member 356 so that it extends a. . . the distal end 360 of the tubular member 356, as shown in FIG. 30C. The free end 259 of the graft vessel 254 is everted and the attachment legs 357 are pierced through the everted wall 259 of the graft vessel 254 to prepare the graft vessel 254 as shown in FIG. 30D. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to help secure the graft vessel 254 in its everted position over the exterior surface of the tubular member 356.

DETDESC:

DETD(83)

After piercing the graft vessel wall 259, the attachment legs 357 of the tubular member 356 are deformed from their axially extending position 357. . . FIG. 30E. For a typical application of the anastomosis fitting 355 in making an end-to-side anastomosis between a saphenous vein graft and the ascending aorta, the radially extending portion 373 of each deployed attachment leg 357' is about 3-4 mm long,. . . is about 2-5 mm long. These dimensions will vary somewhat depending on the size and the wall thickness of the graft vessel and the target vessel to be joined.

DETDESC:

DETD(84)

A . . . the counterbored recess 375 and the annular forming surface 376 provides sufficient clearance for the everted end 259 of the graft vessel 254 when the inner tubular member 356 of the anastomosis fitting 355 is inserted into the counterbored recess 375. The proximal end of the graft vessel 354 extends through a central lumen 378 in the first die 369 and exits the die through a notch. . .

DETDESC:

DETD(85)

The . . . grasped with the special grasping tool 372. The grasping tool 372 has expandable jaws 384, 385 which fit between the graft vessel 354 and the inner lumen 359 of the tubular member 356. The jaws 384, 385 are shaped like sectors. . .

DETDESC:

DETD(86)

Using . . . bent attachment legs 357' and the distal end 360 of the tubular member, with the everted end 259 of the graft vessel 254 attached, are inserted through an opening 267 in the target vessel wall 255 that has previously been made. . . . size of the external diameter of the tubular member 356 to provide compression around the everted end 259 of the graft vessel 254 to help create an anastomotic seal. Since the opening 267 is slightly smaller than the diameter of the. . .

DETDESC:

DETD(87)

Once . . . surface 257 of the target vessel wall 255. This action also serves to approximate the everted end 259 of the graft vessel 254 with the interior surface 257 of the target vessel 255 to effect the desired intimal surface-to-intimal surface approximation. . . . can be made somewhat concave to help create a hemodynamically efficient transition between the target vessel lumen 256 and the graft vessel lumen 249. The self-locking retaining washer 365 of the outer flange 358 locks into the circumferential groove 362 on. . .

DETDESC:

DETD(88)

FIG. . . . a fastening flange 391 which has a central orifice 393 of sufficient size to accommodate the external diameter of the graft vessel 254. The external diameter of a saphenous vein graft used in CABG surgery can range from 3 to 10 mm. The fastening flange 391 and the central orifice 393. . . . configuration. The fastening flange 391 is made with a distal surface 394 over which the free end 259 of the graft vessel 254 is everted, as shown in FIG. 31A. The fastening flange 391 can be made with an annular ridge 395 or with other features on its outer surface to help attach the everted end 259 of the graft vessel 254 to the flange 391. The distal surface 394 of the fastening flange 391 may be contoured to provide a close fit between the everted edge 259 of the graft vessel 254 and the exterior wall 258 of the target vessel 255. If the target vessel 254 diameter is very large compared to the diameter of the graft vessel 254, as in a coronary artery bypass graft to ascending aorta anastomosis, then a planar distal surface 394 on the fastening flange 391 may sufficiently approximate the exterior surface 258 of the target vessel 255. However, if the graft vessel 254 diameter is closer to the diameter of the target vessel 255, as in a bypass graft to coronary artery anastomosis, then the fastening flange 391 should be made with a cylindrical or saddle-shaped contour on the. . . biocompatible material such as stainless steel, titanium alloys, or a biocompatible polymer. The fastening flange 391 acts as an external stent which holds the anastomosis site open and patent, so the flange material is preferably rigid or at least sufficiently resilient. . .

DETDESC:

DETD(89)

The fastening flange 391 with the everted end 259 of the graft vessel 254 attached to it is fastened to the exterior wall 258 of the target vessel 255 with the central. . . 391, traverse from the proximal side 396 to the distal side 394 of the flange 391, then pierce the everted graft vessel wall 259 and the wall of the target vessel 255. It is preferable that the staples 292 pass through. . .

DETDESC:

DETD(90)

The . . . should be sized so that their length corresponds to slightly less than the combined thickness of the flange 391, the graft vessel wall 259 and the target vessel wall 255 so that, when the attachment legs 399 are bent at the. . .

DETDESC:

DETD(91)

The . . . In one embodiment, the staple driver 404 can be tubular with an internal lumen 407 large enough to accommodate the graft vessel 254, allowing the graft vessel 254 to be passed through the staple driver 404 from the proximal end to the distal end. Alternatively, the. . . 404 can be made with a C-shaped cross section with a side opening that is large enough to pass the graft vessel through from the side. The anvil 405 is articulated on the distal end of an elongated shaft 408. The shaft 408 is long and narrow enough to pass through the

lumen 249 of the graft vessel 254 from the free end of the graft. The anvil 405 is passed through the graft vessel lumen 249 in an orientation axially aligned with of the shaft 408 and, once it is in the lumen. . . shaft 408, can be used to center the shaft 408 of the anvil 405 within the lumen 249 of the graft vessel 254 and within the central orifice 393 of the flange 291. The anvil 305 can now be rotated about. . .

DETDESC:

DETD(93)

FIG. . . . includes a fastening flange 412 with a central orifice 413 of sufficient size to accommodate the exterior diameter of the graft vessel 254. A plurality of preformed fastening staples 411 are arranged around the periphery of the fastening flange 412. Preferably,. . .

DETDESC:

DETD(97)

The free end 259 of the graft vessel 254 is everted over the distal surface 422 of the fastening flange 412, as shown in FIG. 32D, and. . . opening 267 in the target vessel 255, an alignment device 423 can be inserted through the lumen 249 of the graft vessel 254 from the opposite end of the graft. The alignment device 423 has a narrow, elongated shaft 424 which fits through the lumen 249 of the graft vessel 254 and an atraumatic centering element 425, such as an inflatable centering balloon on the distal end of the shaft 424. The centering element 425 serves to align the central orifice 413 of the flange 412 and the graft vessel lumen 249 with the opening 267 in the wall of the graft vessel 255. The alignment device 425 can also be used to apply a mild amount of traction on the target vessel wall 255 to better approximate the everted end 259 of the graft vessel 254 and the target vessel 255 when making the anastomosis. Alternatively, the centering element 425 could be replaced with a vessel punch introduced through the graft vessel lumen 249, as in the embodiments described in connection with FIGS. 2-5.

DETDESC:

DETD(98)

Once the everted end 259 of the graft vessel 254 and the target vessel 255 have been properly approximated, the staple driver 426 is advanced distally, as shown in FIG. 32E. The distal ends 416 of the staples 411 pierce the everted graft vessel wall 259 and the target vessel wall 255 and the distal portion 417 of the attachment legs 415 traverses. . .

DETDESC:

DETD(100)

FIGS. . . . alloy. The fastening flange 431 has a central orifice 433 which is sized to accommodate the exterior diameter of the graft vessel 254. The fastening flange 431 has an annular distal ridge 434 and an annular proximal ridge 435 around its. . .

DETDESC:

DETD(101)

The . . . hook-shaped distal segment 441. The distal tip 443 of the hook-shaped distal segment 441 is sharpened to easily penetrate the graft vessel wall 254 and the target vessel wall 255. FIG. 34D shows a slight variation of the staple member 432. . .

DETDESC:

DETD(102)

The anastomosis device 430 is prepared for use by passing the graft vessel 254 through the central orifice 433 of the fastening flange 431 then everting the distal end 259 of the graft vessel 254 over the distal surface 437 of the flange 431. A suture 445 can be tied around the everted end 259 of the graft vessel 254 to secure it to the flange 431. The distal ridge 434 of the flange 431 prevents the tied graft vessel 259 from slipping off of the flange 431. Next, the staple members 432 are straightened and passed through the. . . staples 432 emerge from the distal surface 438 of the flange 431, they pierce the everted wall 259 of the graft vessel 254. At this point the fastening flange 431 with the everted end 259 of graft vessel 254 attached to it is approximated to the exterior surface 258 of the target vessel 255 with the central orifice 433 and the lumen 249 of the graft vessel 254 centered on an opening 267 that has been made in the wall of the target vessel 255. The. . .

DETDESC:

DETD(103)

Once the graft vessel 254 and the target vessel 255 are properly approximated, an annular staple driver 446 is used to push the. . .

DETDESC:

DETD(104)

The . . . a proximal view of the anastomosis device 430 with the staple members 432 deployed. This view is shown without the graft vessel or the target vessel present for the sake of clarity. As best seen in FIG. 33B, the acute angle. . . compression between the flange 431 and the target vessel wall 255 to create a leak proof anastomotic seal between the graft vessel 254 and the target vessel 255.

DETDESC:

DETD(105)

The . . . and press against the vessel wall 255, compressively clamping the fastening flange 431 and the everted end 259 of the graft vessel 254 to the target vessel wall 255. The acute angle of the proximal segment 442 acts like a spring. . .

DETDESC:

DETD(106)

FIGS. . . . flange 448 is a cylindrical member with an internal lumen 450 large enough to accommodate the external diameter of the graft vessel 254. The flange 448 has a distal surface 451 over which the free end 254 of the graft vessel 259 may be everted. An annular ridge 452 around the outer surface of the flange 448 at the distal end helps to hold the everted graft vessel 259 in place and serves as part of a locking mechanism for the attachment staples 449, as will be. . . flange 448. The proximal end 455 of the proximal portion 454 is sharpened for easily piercing the tissue of the graft vessel wall 254. A U-shaped bend 458 connects the proximal portion 454 of the staple 449 to the barbed, pointed. . .

DETDESC:

DETD(107)

The anastomosis device 447 is applied by removing the U-shaped staples 449 from the flange 448. The end 259 of the graft vessel 254 is passed through the internal lumen 450 of the flange 448 until the graft vessel 254 extends a short distance from the distal end 459 of the flange 448. Then, the end 259 of the graft vessel 254 is everted back over the distal end 259 of the flange 448. Once the graft vessel 254 is everted over the flange 448, the staples 449 are reinserted into the holes 456 in the flange 458 by piercing the proximal end 445 through the everted wall 259 of the graft vessel 254. Marks or other visual indications can be provided on the side of the cylindrical flange 448 to aid. . . extend radially outward from the fastening flange 448. The distal surface 459 of the cylindrical flange 448 with the everted graft vessel 259 attached to it is approximated to the exterior surface 258 of the target vessel 255, then the staples. . . 449 passes through the target vessel 255 wall in a linear path, then pierces the everted edge 259 of the graft vessel wall 254 a second time. When the barbed end 453 of staples 449 pass the annular ridge 452 on. . .

DETDESC:

DETD(110)

The . . . deployed by pushing them out the distal end of the flange so that they pass through the wall of the graft vessel into the target vessel, after which, they resume their U shape within the lumen of the target vessel. The. . .

DETDESC:

DETD(111)

FIGS. . . . The inner diameter 484 of the flange fits over a tubular inner member 485 of an application tool 486. The graft vessel 254 is passed through an inner lumen 487 within the tubular member 485 and then the end 259 of the graft vessel 254 is everted over the distal end 488 of the tubular member 485. The application tool 486 is used to approximate the end 259 of the graft vessel 254 to an opening 267 that has previously been made in the wall of the target vessel 255. A. . . which forces the sharpened distal ends 490 of the integral staple legs

483 through the everted wall 259 of the graft vessel 254 and the wall of the target vessel 255. Once the staple legs 483 have traversed the graft vessel 254 and target vessel walls 255, the distal ends 490 of the staple legs 483 are deformed to lock. . .

DETDESC:

DETD(112)

Different . . . An articulating anvil, similar to the one described in FIG. 31A can be inserted through the lumen 249 of the graft vessel 254 to work cooperatively with the staple driver 489 to deform the distal ends 490 of the staple legs. . . temperature to straighten out the distal bends 491. The straightened staple legs 483 are driven through the walls of the graft vessel 254 and the target vessel 255 and the staple legs 483 are heated above their shape-memory transition temperature to. . .

DETDESC:

DETD(115)

The . . . placing first the outer flange ring 498, then the inner flange ring 497 around the distal end 259 of the graft vessel 254. The end 259 of the graft vessel 254 is then everted and approximated to the exterior wall 258 of the target vessel 255 surrounding an opening. . . been previously made in the wall, as shown in FIG. 40C. The inner ring 497 is moved distally along the graft vessel 497 until the points of the staple members 499 contact the everted vessel wall 259. The inner ring 497 is pressed into the everted graft vessel wall 259 and simultaneously rotated in a clockwise direction, thereby driving the staple members 497 through the graft vessel wall 259 and the target vessel wall 255. Next, the outer ring 498 is moved distally along the graft vessel 254 until it is concentric with the inner ring 497. Then the outer ring 498 is pressed into the everted graft vessel wall 259 and simultaneously rotated in a counterclockwise direction, driving the staple members 500 through the graft vessel wall 259 and the target vessel wall 255. When the locking features 501 of the outer ring 498 coincide. . .

DETDESC:

DETD(116)

Alternatively, . . . inner 497 and outer rings 498 of the flange can be applied simultaneously to the everted end 259 of the graft vessel 254 by arranging the rings 497, 498 concentrically, then pressing the staple members 499, 500 into the graft vessel wall 259 while counter-rotating the inner 497 and outer 498 rings. This could best be done with an instrument. . .

DETDESC:

DETD(119)

The . . . to the proximal segment 517. The distal end 520 of the distal segment 519 is sharpened to easily penetrate the graft vessel wall 259.

DETDESC:

DETD(120)

The anastomosis device 503 is prepared by passing the graft vessel 254 through the central orifice 506 of the fastening flange 504 and everting it over the distal surface 508. . . of suture described in previous embodiments of the device, a vessel cap 521 may be used to secure the everted graft vessel 259 to the fastening flange 509. The vessel cap 521 is a toroidal ring with an L-shaped cross section. . . outer diameter of the distal surface 508 of the fastening flange 504 and holds the everted end 259 of the graft vessel 254 in place.

DETDESC:

DETD(121)

Next, the fastening flange 504 with the everted end 259 of the graft vessel 254 attached is approximated to the exterior 258 of the target vessel 255 with the central orifice 506 aligned. . . staple members 505 through the slots 513 in the distal end 508 of the fastening flange 504 to pierce the graft vessel wall 259 and enter the target vessel lumen 256 through the opening 267 in the target vessel wall 255,. . . of the fastening flange 504, as shown in FIG. 41D, to form a leak proof anastomotic seal between the everted graft vessel wall 259 and the target vessel 255.

DETDESC:

DETD(124)

The . . . wire ring 523 with an internal diameter which when fully extended is just slightly larger than the diameter of the graft vessel 254 and of the opening 267 made in the target vessel wall 255. Initially, the wire ring 523 has. . . proximal ends 525 of the staple members 524 are sharpened to easily pierce the target vessel wall 255 and the graft vessel wall 259. Preferably, the proximal ends 525 of the staple members 524 have barbs 526 to improve the security. . .

DETDESC:

DETD(125)

The . . . hold them against the conical holder 529. The application instrument 527 is then inserted through the lumen 249 of the graft vessel 254. This can be done by inserting the instrument through the graft vessel lumen 249 from the proximal to the distal end of the graft vessel 254, or it can be done by backloading the elongated shaft 531 of the instrument into the graft vessel lumen 249 from the distal end to the proximal end, whichever is most convenient in the case. The anvil. . .

DETDESC:

DETD(126)

Next, the distal end 259 of the graft vessel wall 254 is everted against the exterior surface 258 of the target vessel wall 255 with the graft vessel lumen 249 centered on the opening 267 in the target vessel wall 255. The cap 530 is withdrawn from. . . staple members 524' pierce the target vessel wall 255 surrounding the opening 267 and the everted end 259 of the graft vessel 254.

DETDESC:

DETD(127)

The application instrument 527 has an annular staple former 532 which surrounds the outside of the graft vessel 254. Some slight pressure on the everted graft vessel wall 259 from the annular staple former 532 during the piercing step assists in piercing the staple members 524' through the graft vessel walls 259. Care should be taken not to apply too much pressure with the staple former 532 at this. . .

DETDESC:

DETD(128)

Once the staple members 524' have fully traversed the target vessel wall 255 and the graft vessel wall 259, as shown in FIG. 42C, the staple former 532 is brought down with greater force while supporting. . . outward, as shown by the phantom lines 524", so that the sharpened, barbed ends 525 pierce back through the everted graft vessel wall 259 and into the target vessel wall 255 to form a permanent attachment. To complete the anastomosis, the anvil 528 is withdrawn through the graft vessel lumen 249. As the anvil 528 passes through the wire ring fastening flange 523, it straightens out the wave-like. . .

DETDESC:

DETD(129)

FIGS. . . . is generally cylindrical in shape with a central orifice 537 of sufficient diameter to accommodate the external diameter of the graft vessel 254. The wall 538 of the fastening flange has a plurality of holes 539 extending from the proximal surface. . . exterior of the flange 534 close to the distal end 541 of the flange to aid in attachment of the graft vessel wall 254. There is also a circumferential ridge 543 around the exterior of the fastening flange 534 proximal to. . .

DETDESC:

DETD(130)

FIGS. . . . J-shaped hooks 547 ends in a short straight section 548 with a sharpened distal end 546 to easily penetrate the graft vessel 259 and target vessel 255 walls. The staple members 535 should be annealed or cold worked in the illustrated. . .

DETDESC:

DETD(136)

The stapling mechanism 550 is now ready for attachment of the graft

vessel 254 to the fastening flange 534. To begin, the graft vessel 254 is passed through the internal lumen 552 of the holder 553 and the staple driver 559. This can be done by tying a suture around one end of the graft vessel 254, passing the suture through the stapling mechanism 550 and drawing the graft vessel 254 through. Alternatively, an elongated hook or grasping instrument can be inserted through the lumen 552 of the stapling mechanism 550 to draw the graft vessel 254 through. The distal end 259 of the graft vessel 254 is then everted over the distal end 541 of the fastening flange 534.

DETDESC:

DETD(137)

If desired, a loop of suture 564 can be tied around the everted end 259 of the graft vessel 254 at the location of the circumferential notch or groove 542 to secure the graft 259 to the fastening flange 534. The proximal end 565 of the graft vessel 254 can also be everted and temporarily attached with a loop of suture to the proximal extension 561 of the staple driver 559 to make the graft vessel 254 easier to handle.

DETDESC:

DETD(138)

At . . . point, the vessel punch mechanism 551 should be inserted into the stapling mechanism 550 through the lumen 249 of the graft vessel 254. The vessel punch mechanism 551 consists of a housing 566, a cutter 567, an anvil 568, a clamp. . .

DETDESC:

DETD(139)

The . . . an annular clamping surface 588. The proximal end of the clamp shaft 585 is inserted into the cutter 567 and glued or otherwise fastened to the clamp knob 570 which is threaded into the proximal chamber 573 of the housing 566.. . .

DETDESC:

DETD(141)

The . . . 551, as it has just been described, is inserted into the stapling mechanism 550 through the lumen 249 of the graft vessel 254. The clamp 569 of the punch mechanism 551 should be advanced to its farthest distal position before inserting the punch 551 through the graft vessel 254 to avoid damaging the interior wall of the graft vessel 254 with the cutter 567 as it passes through. The set screws 575 in the housing 566 of the. . . corresponding holes 594 in the holder 553 of the stapling mechanism 550 to secure the two interacting mechanisms together. The graft vessel 254 occupies an annular space 595 between the punch mechanism 551 and the interior surface of the stapling mechanism 550. Thus assembled, the anastomosis system, which includes the anastomosis device 533 attached to the graft vessel 254 and the application instrument 536, is prepared to perform an end-to-side anastomosis between the graft vessel 254 and a target vessel 255.

DETDESC:

DETD(142)

The . . . target vessel 255, and the distal edge 541 of the fastening flange 534 with the everted end 259 of the graft vessel 254 attached is approximated to the exterior surface 258 of the target vessel 255, as shown in FIG. 45A.. . .

DETDESC:

DETD(143)

If the anastomosis system is being used to create a proximal anastomosis between a graft vessel and the aorta during a CABG procedure, the clamping feature provides an additional benefit at this point in the. . .

DETDESC:

DETD(144)

In . . . attachment legs 544 emerge from the holes 539, the sharpened distal ends 546 of the attachment legs 544 pierce the graft vessel wall 259 and the short straight section 548 traverses the graft vessel wall 259 in a linear path. Optionally, the staples 535 can be advanced through the graft vessel wall 259 before the graft vessel 259 is approximated to the target vessel 255 so that the surgeon

can verify that all of the staple attachment legs 544 have properly pierced the everted graft vessel wall 259. The sharpened distal ends 546 of the attachment legs 544 then pierce the target vessel wall 255.. . . mechanism 551 supports the target vessel wall 255 and keeps it closely approximated to the everted end 259 of the graft vessel 254 as the staple members 535 penetrate it. As the attachment legs 544 penetrate the target vessel wall 255,. . . legs 544 resume their J shape, as shown in FIG. 45C, firmly attaching the fastening flange 534 and the everted graft vessel 259 to the exterior surface 258 of the target vessel 255.

DETDESC:

DETD(145)

Once the fastening flange 534 and the graft vessel 254 are attached, an opening 267 is made in the target vessel wall 255 by turning the clamp knob. . . to form a fluid communication between the lumen 256 of the target vessel 255 and the lumen 249 of the graft vessel 254. To complete the anastomosis, the fastening flange 534 is released from the holder 553 and the punch mechanism. . .

DETDESC:

DETD(146)

FIGS. . . . a tubular body 606 which has an internal lumen 607 of sufficient diameter to accommodate the external diameter of the graft vessel 254. Attached to the distal end of the tubular body 606 is an inner flange 601 over which the free end 259 of the graft vessel 254 will be everted. On the proximal end 610 of the tubular body 606 are three radially extending lugs. . .

DETDESC:

DETD(150)

The . . . members 603 into the holes 613. The anastomosis device 600 is now prepared to perform an end-to-side anastomosis between a graft vessel 254 and the wall of a target vessel 255 as follows.

DETDESC:

DETD(151)

To begin, the graft vessel 254 is inserted through the central lumen 607 of the fastening flange 605 and the internal lumen 632 of. . . mechanism 604 by drawing it through with a suture or an elongated grasping instrument. The distal end 259 of the graft vessel 254 is then everted over the inner flange 601 on the distal end 611 of the fastening flange 605. The inner flange 601 with the everted end 259 of the graft vessel 254 attached is inserted through an opening 267 in the target vessel wall 255 that has previously been made. . . advanced distally, causing the sharpened ends 621 of the staple members 603 to pierce the everted wall 259 of the graft vessel 254 and enter the lumen 256 of the target vessel 256. As the staple members 603 emerge from the. . . a smooth, hemodynamically efficient connection between the lumen 256 of the target vessel 255 and the lumen 249 of the graft vessel 254. The stapling mechanism 604 is now removed by rotating the outer sleeve 625 to release its grasp on. . .

DETDESC:

DETD(152)

FIGS. . . . has a ring-shaped bushing 638 with an internal diameter 639 of sufficient size to accommodate the exterior diameter of the graft vessel 254. A plurality of deformable attachment legs 637, six in this exemplary embodiment, are attached to the proximal end. . . vessel wall 255. The length of the attachment legs 637 can be varied to accommodate different wall thicknesses of the graft vessels 254 and target vessels 255 to be attached.

DETDESC:

DETD(154)

The ring-shaped bushing 638 has a distal surface 644 over which the end 259 of the graft vessel 254 will be everted. The distal end 644 of the ring-shaped bushing 638 is flared out slightly to provide a more secure attachment of the everted end 259 of the graft vessel 254 to the bushing 638. There are a plurality of axial holes 645 in the wall of the ring-shaped. . .

DETDESC:

DETD(157)

An . . . surface 660 on its distal end. The inner staple driver 659 has an internal lumen 662 that can accommodate the graft vessel 254 during the anastomosis procedure. The gripper 652, the actuator/driver 655 and the inner staple driver 659 are held. . .

DETDESC:

DETD(159)

At this point the graft vessel 254 is passed through the internal lumen 662 of the staple applying instrument 648 until a short length of the graft 254 extends from the distal end of the instrument 635. The end 259 of the graft 254 is then everted over the distal surface 644 of the ring-shaped bushing 638. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to secure it to the bushing 638. The staple instrument 635, with the everted end 259 of the graft vessel 254 attached, is approximated to the exterior surface 258 of the target vessel 255 where an opening 267 in. . .

DETDESC:

DETD(160)

The . . . opening 267 in the target vessel wall 255 to approximate the intimal surface on the everted end 259 of the graft vessel 254 with the intimal surface 257 of the target vessel 255, as shown in FIG. 49A. Preferably, the opening. . . the locked position and advanced distally to drive the inner staple members 636 through the everted wall 259 of the graft vessel 254. As the staple members 636 exit the axial holes 645 in the bushing 638, they resume their J-shaped. . . the tissue and compressing it against the exterior of the ring-shaped bushing 638 and the everted edge 259 of the graft vessel 254 to form a leak-proof anastomotic seal, as shown in FIG. 49C. The actuator/driver 655 is withdrawn in the. . .

DETDESC:

DETD(161)

FIG. . . . that the mismatch in vessel compliance between the target vessels, which include the aorta and the coronary arteries, and the graft vessel, typically a saphenous vein, can contribute to the development of intimal hyperplasia, stenosis and occlusion in the graft vessel, especially at the anastomosis where the compliance mismatch is most apparent. Joining a highly compliant vessel, such as a. . . for mismatched compliance at an anastomosis site is the joining of a compliant blood vessel with a highly noncompliant artificial graft vessel. Additionally, turbulence in the blood flow at the anastomosis site may exacerbate the problem, accelerating the stenosis process. It. . .

DETDESC:

DETD(162)

Another concern in anastomosis procedures is to create a gradual curve in the graft vessel leading away from the anastomosis site. This is sometimes necessary because the most convenient angle for attaching the graft vessel to the target vessel does not match the desired path for the graft vessel away from the anastomosis. For instance, in CABG surgery the desired path for the graft vessel is often parallel to the ascending aorta, however the graft vessel must be joined to the ascending aorta at some angle in order to create the anastomosis. Creating a gradual curve leading away from the anastomosis site to avoid kinking or narrowing of the graft vessel lumen is sometimes problematic. This is especially true when the graft vessel is joined at right angles to the ascending aorta. It would be desirable therefore to provide the anastomosis devices with a reliable means to create a gradual curve in the graft vessel leading away from the anastomosis site.

DETDESC:

DETD(163)

The . . . flexible tubular member 668 which can be appended to the proximal end of the anastomosis device 669 to support the graft vessel 254 leading away from the anastomosis site. The flexible tubular member 668 may have any or all of gradually. . . decreasing stiffness, increasing compliance and increasing diameter as it extends proximally from the anastomosis device 669. This will give the graft vessel 254 a gradual curve, a gradual change in its radial compliance, and a gradual change in diameter from the. . .

DETDESC:

DETD(170)

A . . . 54. This catheter device 691 is configured to be delivered to the anastomosis site through the lumen 249 of the graft vessel 254 which has a number of potential advantages. First, the device 691 can be used without the need for. . . the need for fluoroscopic imaging. Third, the T-shaped configuration of the catheter 691 can help to facilitate approximation of the graft vessel 254 and the target vessel 255 during the anastomosis procedure.

DETDESC:

DETD(172)

In operation, the T-shaped distal end 693 of the catheter is passed through the lumen 249 of the graft vessel 254 with the balloons 696, 697 deflated. An incision 700 is made in the wall of the coronary artery. . .

DETDESC:

DETD(173)

With the anastomosis site 700 isolated from the blood flow, the graft vessel 254 can be approximated to the target vessel with the T-shaped catheter body 693 providing a guide for the. . . anastomosis is complete, the balloons 696, 697 can be deflated and the catheter withdrawn through the lumen 249 of the graft vessel 254.

DETDESC:

DETD(180)

The graft is then attached to the opening in the coronary artery. The graft is preferably cut at an angle to form an oval-shaped opening having a heel and a toe. The heel is. . . attached to the coronary artery and sutures are placed from the heel to the toe on one side of the graft. Sutures are then placed on the other side of the graft.

DETDESC:

DETD(182)

Referring . . . elongate tubular portion 830 and a flared end 832. The removal device 828 prevents tearing or pulling of the sutures, graft and coronary artery when the coronary shunt is removed. The removal device 828 is particularly useful when the inflation tube. . . removal device 828 may have any shape, such as a T-shape, which prevents the coronary shunt from contacting the sutures, graft or coronary artery when removed.

DETDESC:

DETD(183)

Referring . . . the flared end 832. The removal device 828 advantageously prevents the coronary shunt from exerting tearing forces on the sutures, graft or coronary artery. After the coronary shunt has been removed, the removal device 828 is withdrawn and the anastomosis is. . .

DETDESC:

DETD(187)

Use . . . and in the depressions 834 to occlude the coronary artery around the shunt 800A. The surgeon then begins attaching the graft to the coronary artery. When the anastomosis is nearly complete, the coronary shunt 800A is separated into the first and. . .

DETDESC:

DETD(203)

Two . . . wire 861 coated with a polymer 863. The wire 861 is preferably a 0.004 inch diameter stainless steel wire or ribbon coated with polyurethane to a thickness of between 0.002 and 0.004 inch. The filaments 860 preferably have a circular cross-sectional. . .

DETDESC:

DETD(205)

Use . . . opening in the coronary artery and two filaments 860 extending through the tube 858. The surgeon then begins attaching the graft to the coronary artery until the anastomosis is nearly

complete. The surgeon then grasps one, or both, of the filaments. . .

DETDESC:

DETD(207)

A . . . and methods of the present invention will now be described in relation to performing a proximal anastomosis on a free graft during a closed-chest or port-access coronary artery bypass graft surgical procedure. Closed-chest or port-access coronary artery bypass graft (CABG) surgery is a newly developed procedure designed to reduce the morbidity of CABG surgery as compared to the standard. . . for a median sternotomy or other gross thoracotomy as is required in open-chest CABG surgery. A port-access coronary artery bypass graft surgical procedure using sutured anastomosis techniques is more fully described in co-pending patent applications Ser. Nos. 08/023,778 and 08/281,891, which. . .

DETDESC:

DETD(209)

Meanwhile a graft vessel is prepared for creating the bypass graft which will redirect blood flow from the ascending aorta to one or more of the coronary arteries downstream of any. . . mammary arteries or the gastro-epiploic artery, and artificial grafts, such as Dacron or Goretex (expanded PTFE) grafts. If an autologous graft, such as a vein or an artery, is to be used, the vessel is generally harvested from the patient at. . .

DETDESC:

DETD(210)

Depending on the preference of the surgeon, the proximal anastomosis, which joins the graft vessel to the aorta, can be performed before or after the distal anastomosis, which joins the graft vessel to one or more of the coronary arteries. The distal anastomosis is generally performed while the patient's heart is. . .

DETDESC:

DETD(212)

By . . . the vessel punch 120 and the punch 120 is removed along with the tissue 153 excised by the punch. The graft insertion tool 121 and the graft vessel 148, which has previously been prepared with the coupling member 102 as shown in FIG. 6 by everting the distal end of the graft vessel 148 over the coupling member 102, are then inserted though the access port 702, as shown in FIG. 56, and the graft vessel 148 is attached to the ascending aorta 707 at the anastomosis site 706 by inserting the coupling member 102. . .

DETDESC:

DETD(213)

The bypass operation is then completed by anastomosing the distal end 708 of the graft vessel to the coronary artery 709 below the stenosis or occlusion, as shown in FIG. 57. The distal anastomosis can be performed using suturing techniques or the graft vessel 148 can be joined to the coronary artery 709 using a second anastomosis staple by following the steps shown in FIGS. 5A-5C and FIG. 7C, using the embodiment of the graft insertion tool 122 illustrated in FIGS. 7A-7C.

DETDESC:

DETD(214)

Alternatively, . . . order, as is preferred by some cardiac surgeons. In this case the distal anastomosis would be performed first, using the graft insertion tool 121 of FIGS. 6A-6C, followed by the proximal anastomosis performed using the graft insertion tool 122 of FIGS. 7A-7C. When performing the proximal anastomosis as the second anastomosis on a free graft, both ends of the graft vessel can be prepared for anastomosis by attaching a coupling member 102 to the proximal and the distal end of the graft vessel 148 and inserting the graft vessel 148 into the chest cavity of the patient through one of the access ports 702 after attaching anchor members. . . 101 using the appropriate insertion tool 121, 122. An alternate technique is to first attach the distal end of the graft vessel 148 to a coronary artery 709 using an anastomosis staple or sutures, according to the preference of the surgeon, then, after verifying the correct length of the graft vessel, drawing the proximal end 710 of the graft vessel 148 out of the chest cavity through one of the access ports 702. The free proximal end 710 of the graft vessel 148 can be prepared under direct vision

by the surgeon by passing the free end of the graft vessel through the lumen of the coupling member 102 and everting it over the distal end 115 of the coupling member 102. The coupling member 102 with the proximal end 710 of the graft vessel attached can be reinserted into the chest cavity through the access port 702 and inserted into an anchor member 101 attached to the aortic wall 707 using the graft insertion tool 122 of FIGS. 7A-7C. This same technique can be used with the two-piece anastomosis staple for performing a distal anastomosis on a pedicled graft vessel or for performing a distal anastomosis on a free graft after the proximal anastomosis has already been made.

DETDESC:

DETD(215)

The . . . one-piece anastomosis staples of FIGS. 9, 10, 11 or 12 can also be understood in relation to FIGS. 55-57. The graft vessel 148 and the one-piece anastomosis staple 163 are prepared as described above in relation to FIGS. 13 and 14.. . . the actuating plunger to advance the tubular cutter over the anvil. The staple applying tool of FIG. 13 with the graft vessel 148 everted over the distal tubular extension 166 of the anastomosis staple 163, as shown in FIG. 14, is. . .

DETDESC:

DETD(216)

As . . . the one-piece anastomosis staple of FIG. 9 can also be used for creating the proximal and/or distal anastomoses on a graft vessel in either order, according to the preference of the surgeon. When performing the second anastomosis on a free graft or the distal anastomosis on a pedicled graft, the free end of the graft vessel can be drawn out of the chest cavity through one of the access ports to prepare the end of the graft vessel under direct vision by the surgeon. The graft vessel is prepared by passing the free end of the graft vessel through the lumen of the anastomosis staple and everting it over the distal flange. The anastomosis staple with the free end of the graft vessel attached can be reinserted into the chest cavity through the access port and attached to the wall of the. . .

DETDESC:

DETD(217)

Although . . . Any one of the one or two-piece embodiments of the anastomosis staple device can be supplied preattached to a prosthetic graft vessel. For instance, the two-piece anastomosis staple device could be supplied in a kit, including a natural or artificial graft that is prepared with a coupling member attached to one or both ends and one or two anchor members for. . . the target vessel(s). Likewise, the one-piece anastomosis staple device can be supplied in a procedural kit preattached to a prosthetic graft vessel. This is equally applicable to artificial graft materials, such PTFE or Dacron grafts, or to natural biological graft materials, including allografts of human graft vessels, or xenografts such as bovine or porcine graft vessels, either freshly harvested, glutaraldehyde treated or cryogenically preserved. An anastomotic device application instrument, such as those described above, could. . .

CLAIMS:

CLMS(1)

We . . .
second sides of the opening so that fluid flow between the hollow body structure and the shunt is prevented;
attaching a graft vessel to the opening in the coronary artery; and
removing the shunt through the opening in the coronary artery before completing. . .

CLAIMS:

CLMS(5)

5. The method of claim 4, further comprising the step of:
attaching a graft to the hollow body structure.

US PAT NO: 5,755,777 [IMAGE AVAILABLE] L1: 12 of 37
TITLE: Expandable transluminal graft prosthesis for repair of aneurysm

ABSTRACT:
A transluminal grafting system for grafting a prosthesis to the wall of a lumen includes a tubular graft provided with spring assemblies and anchoring barbs. The prosthesis is mounted on an apertured tubular carrier and a central control. . . and engage the central control means. An introducer sheath covers the system for smooth insertion into a

lumen. When the graft has been positioned, the central control means maintains the axial position of the prosthesis. When the introducer sheath is pulled, the prosthesis is exposed and the spring assemblies return to an expanded state and anchor the graft against the internal wall of the lumen.

PARENT-CASE:

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 08/173,148 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Dec. 22, 1993, now U.S. Pat. No. 5,562,726, which is a continuation-in-part of application Ser. No. 07/868,792 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Apr. 15, 1992, now abandoned, which is a continuation-in-part of Ser. No. 07/782,696 for an Expandable Transluminal Graft Prosthesis for Repair of Aneurysm and Method for Implanting, filed Oct. 25, 1991, now abandoned.

SUMMARY:

BSUM(2)

The invention relates to transluminal graft prostheses for the repair of aneurysms and a method for implanting them.

SUMMARY:

BSUM(4)

The . . . incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

SUMMARY:

BSUM(5)

Such . . . The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant. . .

SUMMARY:

BSUM(7)

U.S. . . . is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to. . .

SUMMARY:

BSUM(8)

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on. . . to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts. . . repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

SUMMARY:

BSUM(9)

The . . . of Diagnostic Radiology, University of Texas M.D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming. . . compressed radially, and is introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the catheter while holding the introducer wire stationary. This. . . rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one of these grafts carried barbs. The other model showed. . . a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter.. . .

SUMMARY:

BSUM(10)

Endovascular . . . lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

SUMMARY:

BSUM(11)

The . . . this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY:

BSUM(13)

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

SUMMARY:

BSUM(16)

The . . . of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . .

SUMMARY:

BSUM(17)

The . . . lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of.

. . device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and. . .

SUMMARY:

BSUM(18)

The . . . assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end,. . .

SUMMARY:

BSUM(21)

The . . . and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally. . .

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a tubular graft of the instant invention;

DRAWING DESC:

DRWD(7)

FIG. 6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

DRAWING DESC:

DRWD(17)

FIG. 15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

DRAWING DESC:

DRWD(19)

FIG. 18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

DRAWING DESC:

DRWD(21)

FIG. 20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

DRAWING DESC:

DRWD(22)

FIG. 21 depicts a segment of a self-expanding stent;

DRAWING DESC:

DRWD(23)

FIG. 22 depicts a bifurcated graft;

DRAWING DESC:

DRWD(27)

FIG. 28 depicts tubular extensions sutured to a graft of the present invention;

DRAWING DESC:

DRWD(28)

FIG. 29 depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

DRAWING DESC:

DRWD(36)

FIG. 39 depicts a distal stent insertion device of the present invention;

DETDESC:

DETD(2)

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron.TM.), which is known to be. . . material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

DETDESC:

DETD(3)

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide. . . a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

DETDESC:

DETD(4)

The . . . 60 respectively. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurved arches 42 is that they collapse more readily and are more durable.. . . barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such. . . have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft 1 would be in less intimate contact with the wall of the lumen.

DETDESC:

DETD(5)

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that is. . . and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact. . . both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the graft 1 to provide a more secure anchor in the direction of blood

flow. The barbs 10 are positioned so that. . .

DETDESC:

DETD(6)

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to. . . overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has. . .

DETDESC:

DETD(7)

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGS. 9-A and 9-B, the joint is more flexible when the spring assemblies 64. . . . Thus, because .alpha. is larger than .beta., the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

DETDESC:

DETD(10)

FIG. . . . tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath. . .

DETDESC:

DETD(11)

"Muzzle loading" involves inserting the graft 1, already mounted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4. . .

DETDESC:

DETD(12)

37 . . . loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to. . . totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

DETDESC:

DETD(13)

The . . . over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially. . .

DETDESC:

DETD(14)

FIG. . . . iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted in the aorta 2 at the site of the aortic aneurysm 20.

DETDESC:

DETD(15)

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled,. . .

DETDESC:

DETD(18)

In . . . into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

DETDESC:

DETD(21)

All . . . devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1 during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including. . . of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially. . .

DETDESC:

DETD(22)

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

DETDESC:

DETD(23)

The . . . of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly. . . tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring. . . means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may. . . 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a. . . of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer. . .

DETDESC:

DETD(24)

FIG. . . . catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

DETDESC:

DETD(25)

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft

against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the. . .

DETDESC:

DETD(26)

The . . . open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy. . . sheath 4 is pulled back exposing the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass. . . tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn. . . and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present). . . past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26,. . .

DETDESC:

DETD(27)

Aortic . . . iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such. . . contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends. . .

DETDESC:

DETD(28)

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

DETDESC:

DETD(30)

When . . . percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

DETDESC:

DETD(31)

Hereinafter described is a bifurcated endovascular graft 150 and the method of insertion thereof for repair of abdominal aortic aneurysm.

Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

DETDESC:

DETD(32)

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

DETDESC:

DETD(33)

All . . . the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

DETDESC:

DETD(34)

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251. . .

DETDESC:

DETD(35)

Grafts . . . may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

DETDESC:

DETD(36)

In . . . common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

DETDESC:

DETD(37)

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with. . . fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

DETDESC:

DETD(46)

The . . . control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGS. 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

DETDESC:

DETD(47)

As . . . FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches. . . suture 252 and 253 that pass along the wall of respective tubular extensions 246 and 247 to the junction with graft 206.

DETDESC:

DETD(48)

Alternatively, . . . caudal limb control suture 154 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256. . . and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when. . .

DETDESC:

DETD(49)

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter. . .

DETDESC:

DETD(50)

As . . . traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216. . .

DETDESC:

DETD(51)

As . . . used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 254 is also required on ipsilateral distal limb 213.

DETDESC:

DETD(54)

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

DETDESC:

DETD(55)

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external. . . sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath.. . . of the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of caudal stent 275.

DETDESC:

DETD(56)

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. straightening device 130 is advanced over the distal limb control system onto the end of the distal. . . of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

DETDESC:

DETD(57)

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132. . . maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the. . . reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

DETDESC:

DETD(62)

An . . . that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in. . .

DETDESC:

DETD(63)

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method, a Dormier basket is passed up the ipsilateral. . .

DETDESC:

DETD(65)

The . . . of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath 217 exposes the caudal limb control mechanisms and their. . . carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral. . .

DETDESC:

DETD(67)

Stents . . . required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used,. . . is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

DETDESC:

DETD(68)

The . . . the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory,. . .

CLAIMS:

CLMS(9)

9. The delivery system of claim 3 further comprising a caudal stent insertion device insertable in a limb bore of said self-expanding prosthesis, said insertion device including an outer sheath, a stent pusher positionable within said outer sheath and having a stem for

positioning a caudal stent therearound when in said outer sheath.

CLAIMS:

CLMS(14)

14. The delivery system of claim 13 further comprising a caudal stent insertion device insertable in a limb bore of the self-expanding prosthesis, said insertion device including an outer sheath, a stent pusher positionable within said outer sheath and having a stem for positioning a caudal stent therearound when in said outer sheath.

US PAT NO: 5,741,323 [IMAGE AVAILABLE] L1: 13 of 37

SUMMARY:

BSUM(7)

Typically, . . . fluid. In that method, heat is conducted from the fluid in the balloon, through the balloon material, and into the stent. Since conduction is a relatively slow process and the balloon has a relative large thermal mass, energy is transferred not only to the stent, but also to the surrounding body tissues and fluids. The result is that undesired amounts of heat are transferred into. . .

SUMMARY:

BSUM(12)

The resulting shaped article provides a therapeutic benefit by acting, in one embodiment, as a stent to maintain patency through a blood vessel. Numerous other therapeutic shapes are contemplated as well.

DETDESC:

DETD(36)
G. Polyoxyalkylenes, where alkene is 1 to 4 carbons, as homopolymers and copolymers including graft copolymers.

DETDESC:

DETD(56)

In one embodiment, the polymeric material may comprise a stent that is applied to the interior of a blood vessel following treatment of a stenosis by angioplasty. In that embodiment,. . .

DETDESC:

DETD(89)

The . . . is guided to a treatment location. Alternatively, other mechanical means such as end caps, or other retainers known in the stent art may be used to retain the article on the balloon. In particular, retaining sleeves or grommets of silicone or. . .

DETDESC:

DETD(108)

For . . . foreign material (i.e., polymer) placed into the blood vessel. Perforations may encourage more rapid and complete encapsulation of the polymeric stent, which may be desired to prevent distal embolization.

DETDESC:

DETD(109)

The . . . surfaces to prevent the formation of connective tissue following trauma or surgical injury, or the material may be used to adhere tissue surfaces to other tissues or implants. In one embodiment, the adherent properties of the materials may be used to join severed nerve endings. These and other applications are described in detail. . .

DETDESC:

DETD(132)

Devices, . . . (1050 micron) mandrel to obtain a roll about 10 mm long along the mandrel. The roll was secured with Teflon tape and heat set at 50 degrees C. at least 12 hours. The rolled devices were cold sterilized with ethylene oxide. . .

CLAIMS:

CLMS(17)

17. An article as in claim 15, wherein the article is on at least partially preformed stent, paving, or coating.

CLAIMS:

CLMS(18)

18. An article as in claim 17, wherein the article is a partially preformed stent.

US PAT NO: 5,735,892 [IMAGE AVAILABLE] L1: 14 of 37
TITLE: Intraluminal stent graft

ABSTRACT:
A tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene which is less than 0.10 mm thick. The covering may be on the exterior surface of the stent, or on the interior surface of the stent, or both. The covering may be affixed to the stent by an adhesive which is preferably fluorinated ethylene propylene.

SUMMARY:

BSUM(5)

Alternative methods have evolved which use intraluminal vascular grafts in the form of adjustable stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by. . .

SUMMARY:

BSUM(6)

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

SUMMARY:

BSUM(8)

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at. . . location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of adjustable stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

SUMMARY:

BSUM(9)

Intraluminal . . . No. 3,657,744 to Ersek describes a method of using one or more adjustable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

SUMMARY:

BSUM(10)

Choudhury, U.S. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terephthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

SUMMARY:

BSUM(11)

Rhodes, . . . sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX.RTM. Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff Ariz.) or Impra.RTM. Graft (Impra, Inc. Tempe Ariz.). Both the GORE-TEX Vascular Graft

and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra graft as the sleeve component is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the. . . insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of manufacturing an extruded, longitudinally expanded. . .

SUMMARY:

BSUM(13)

The present invention is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular covering of porous expanded PTFE film affixed to the stent, said covering being less than about 0.10 mm thick.

SUMMARY:

BSUM(14)

Porous . . . type as taught by U.S. Pat. No. 4,776,337 which typically require a balloon catheter to increase the diameter of the stent within a blood vessel. The term self-expanding refers to stents which increase in diameter by various other means. Stents of. . .

SUMMARY:

BSUM(15)

The . . . covering of porous expanded PTFE film may be affixed to either the exterior surface or the luminal surface of the stent. Alternatively, a first tubular covering of porous expanded PTFE film may be affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded PTFE film may be affixed to the luminal surface of the tubular diametrically adjustable stent. The first and second tubular coverings of porous expanded PTFE film may be affixed to each other through the openings through the wall of the stent.

SUMMARY:

BSUM(16)

The porous expanded PTFE film may be affixed to the stent with an adhesive. The adhesive may be a thermoplastic adhesive and more preferably a thermoplastic fluoropolymer adhesive such as fluorinated. . . and second tubular coverings of expanded PTFE film are affixed to each other through the multiplicity of openings in the stent wall, the two coverings may be affixed by heating them above the crystalline melt point of the PTFE film adequately to cause them to thermally adhere, or alternatively they may be affixed by an adhesive such as FEP.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent.

DRAWING DESC:

DRWD(5)

FIG. 4 is a transverse cross section of the stent of Example 1 having a luminal layer of porous expanded PTFE film with longitudinally-oriented fibrils and an exterior layer of. . .

DRAWING DESC:

DRWD(6)

FIG. 5 is a transverse cross section of the stent of Example 2 having a luminal layer of porous expanded PTFE film with biaxially-oriented fibrils.

DRAWING DESC:

DRWD(7)

FIG. 6 is a transverse cross section of the stent of Example 3 having an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

DRAWING DESC:

DRWD(8)

FIG. 7 describes a method of collapsing a previously outwardly adjusted balloon-expandable stent.

DRAWING DESC:

DRWD(9)

FIG. 8 describes the fitting of a single tubular sleeve to both the exterior and luminal surfaces of a stent.

DRAWING DESC:

DRWD(10)

FIG. 9 describes the removal a covered, braided wire stent of the self-expanding type from a manufacturing mandrel by everting the braided wire, thereby placing the covering on the luminal surface of the stent.

DETDESC:

DETD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. While the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be. . .

DETDESC:

DETD(3)

The stent may be provided with an exterior covering of porous expanded PTFE film, or a luminal covering of porous expanded PTFE. . .

DETDESC:

DETD(6)

Wall thickness measurements of intraluminal graft stent coverings were determined by cutting away a portion of the covering that covered an opening through the stent wall. The thickness of the sample portion was measured by placing the sample portion between the pads of a Mitutoyo. . .

DETDESC:

DETD(7)

The following examples of intraluminal stent grafts are intended to be illustrative only and are not intended to limit the scope of the invention to only. . .

DETDESC:

DETD(9)

A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film. This 3 cm long stent was formed from 0.25 mm diameter Nitinol wire into a tubular shape of interlocking hexagons. The luminal and exterior coverings. . . to each other. The luminal covering was provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering was provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the luminal and exterior coverings was a porous expanded PTFE film having a discontinuous, porous. . .

DETDESC:

DETD(17)

A . . . axis of the mandrel; the FEP-coated side of the film faced away from the surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The 3 cm length of the stent was centered over the 3.0 cm length of film-wrapped mandrel. The stent was then provided with an exterior covering 47 of a 3.0 cm wide tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so

that the edges of the circumferentially-wrapped tape overlapped by about 3 mm to form seam 49. The circumferentially wrapped covering was oriented so that the FEP-coated side of the tape faced inward in contact with the exterior surface of the stent and the outward facing FEP-coated surface of the luminal layer of film exposed through the openings in the stent. Except for the overlapped seam edges 49, the circumferentially-wrapped covering was only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape were circumferentially-oriented about the exterior stent surface.

DETDESC:

DETD(18)

The . . . from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the film-wrapped stent. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the luminal layer of film was adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the stent. The combined thickness of the luminal and exterior coverings was about 0.025 mm.

DETDESC:

DETD(19)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(21)

A Nitinol wire stent of the same type used for Example 1 was provided with a luminal covering of a porous expanded PTFE film. . . had a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The mandrel assembly was then placed into an oven set. . . at 360.degree. C. for four minutes. After removal from the oven and subsequent cooling, the mandrel was removed from the stent leaving the wrapped film adhered to the luminal surface of the stent. This film was then peeled from the luminal stent surface, leaving the FEP-coating and some small shreds of residual porous expanded PTFE adhered to the luminal surface of the stent wires. By removing the film and leaving the FEP adhesive on the luminal stent surface, the film served only as a release substrate for the application of the adhesive to the stent surface.

DETDESC:

DETD(23)

The . . . contacted with the surface of a hand-held iron set at 400.degree. C. to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam was trimmed away and discarded. The stent was again carefully fitted over the film-covered mandrel. The resulting assembly was placed into an oven set at 380.degree. C. for three minutes and then removed and allowed to cool, after which the mandrel was removed from the stent. The porous expanded PTFE film appeared to be well adhered to the luminal surface of the wire stent by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film. . .

DETDESC:

DETD(24)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(26)

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) was adjusted from its collapsed. . . 8.0 mm by inserting a tapered stainless steel mandrel followed by a straight 8.0 mm diameter stainless steel mandrel. This stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. This was accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the stent. This exterior covering 61 is described by the transverse cross section of FIG. 6. A 2 mm wide seam 45. . . over these edges and applying heat from a hand-held iron with a surface temperature of about 400.degree. C. The film-wrapped stent 65 was then placed into an oven set at 380.degree. C. for 3 minutes, after which it was removed and allowed to cool. The film appeared to be well adhered to the exterior surface of the stent. The wall thickness of the film covering was about 0.01 mm. The enlarged stent was then collapsed by the following process.

DETDESC:

DETD(27)

A series of 20 cm long 6-0 sutures were tied individually to each of the closed metal stent openings adjacent to one end of a stent. The film-covered stent was provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping was intended as a dry lubricant. As described by FIG. 7 which omits the exterior film covering for clarity, the enlarged stent 71 was then pulled by these sutures 77 through a tapered die 75 of round cross section and 2.5 cm. . . bore at its entrance 78 and a 4.5 mm diameter bore at its exit 79. The result was that the stent was collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous expanded PTFE film aided in making it possible to pull the stent through the die. This temporary covering was removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an appropriately sized, smaller diameter exit bore would result in collapsing the stent to its original collapsed diameter. The film-covered stent was again enlarged to a diameter of 8 mm using a balloon catheter followed by a tapered stainless steel mandrel.. . . The covering of porous expanded PTFE film appeared to be fully intact after the collapsing and enlarging of the film-covered stent.

DETDESC:

DETD(28)

Stent coverings may be affixed to a stent surface by variations on this method. For example, a tubular sleeve may be made from a film of porous expanded PTFE and inverted back into itself and fitted over the inner and outer surfaces of a stent as shown by FIG. 8. The inner 83 and outer 85 portions of the tubular sleeve 81 may be thermally adhered to each other through the openings in the stent wall, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends 87 of the tube together.

DETDESC:

DETD(30)

A . . . single layer, approximate 1 mm overlap covering of porous expanded PTFE film by helically wrapping the wire with a narrow tape cut from a sheet of porous expanded PTFE film. The tape used was 6 mm wide, 0.01 mm thick, 0.3 g/cc density, and had uniaxially-oriented fibrils of about 50 micron fibril length. This tape-covered wire was then heated by pulling the wire through the 0.14 mm diameter orifice of a 2.5 cm long die heated to 400.degree. C., at a rate of 1.5 meters per minute, thereby adhering the overlapped edges of the tape together and thereby adhering the tape to the wire. This wire was then cut into shorter lengths and spooled onto 16 bobbins. These bobbins were used. . .

DETDESC:

DETD(31)

A . . . a braided covering of the above wire was applied at a density of about 16 picks/cm. An additional covering of tape cut from a sheet of porous expanded PTFE film was then helically wrapped over the surface of the wire-braided PTFE mandrel. The tape used for this helical wrapping was of 0.01 mm thickness, 0.3 g/cc density, about 50 micron fibril length and 12. . . C. for four minutes, after which it was

removed and allowed to cool. As shown by FIG. 9, the wire-braided stent 91 with the exterior covering of porous expanded PTFE tape was then removed from the non-porous PTFE mandrel 93 by folding the ends 95 of the braided wires back on. . . the braided assembly from the mandrel resulted in the helical wrapping of film being located on the lumen of the stent. This construction offered good self-expanding characteristics in that when longitudinal tension was placed on the stent, the length of the stent increased and the diameter decreased. Upon release of tension, the stent immediately recovered its previous shorter length and larger diameter. This film-covered stent is therefore expected to be useful as a self-expanding stent.

CLAIMS:

CLMS(1)

We claim:

1. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) a first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal. . . surface; and
c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal. . .
wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm,thick exclusive of the stent.

CLAIMS:

CLMS(2)

2. A tubular intraluminal graft according to claim 1 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

CLAIMS:

CLMS(3)

3. A tubular intraluminal graft according to claim 2 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering. . .

CLAIMS:

CLMS(4)

4. A tubular intraluminal graft according to claim 3 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(5)

5. A tubular intraluminal graft according to claim 1 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

CLAIMS:

CLMS(6)

6. A tubular intraluminal graft according to claim 5 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(7)

7. A tubular intraluminal graft according to claim 1 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable

stent.

CLAIMS:

CLMS(8)

8. A tubular intraluminal graft according to claim 2 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(9)

9. A tubular intraluminal graft according to claim 1 wherein the tubular diametrically adjustable stent is a Nitinol stent.

CLAIMS:

CLMS(10)

10. A tubular intraluminal graft according to claim 1 wherein the stent is a balloon-expandable stent.

CLAIMS:

CLMS(11)

11. A tubular intraluminal graft according to claim 1 wherein the stent is a self-expanding stent of braided wire.

CLAIMS:

CLMS(12)

12. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) affixing a first tubular covering to the exterior surface and a second tubular covering to the luminal surface, said first. . .

CLAIMS:

CLMS(15)

15. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface, an end edge and a wall, and having a multiplicity of openings through the wall of the stent;
b) a tubular covering of porous expanded polytetrafluoroethylene affixed to the tubular, diametrically adjustable stent;
wherein the tubular covering of porous expanded polytetrafluoroethylene is folded over the end edge of the tubular, diametrically adjustable stent and is affixed to the exterior surface and the luminal surface of the tubular diametrically adjustable stent, and wherein the folded tubular covering has a thickness less than about 0.10 mm thick exclusive of the stent.

CLAIMS:

CLMS(16)

16. A tubular intraluminal graft according to claim 15 wherein the tubular covering is affixed by an adhesive.

CLAIMS:

CLMS(17)

17. A tubular intraluminal graft according to claim 15 wherein the tubular covering is affixed with sutures.

CLAIMS:

CLMS(18)

18. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;

b) a first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal. . . surface; and

c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent, and having an exterior surface, a luminal surface and a seam extending from the exterior surface through to the luminal. . .

CLAIMS:

CLMS(19)

19. A tubular intraluminal graft according to claim 18 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

CLAIMS:

CLMS(20)

20. A tubular intraluminal graft according to claim 19 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(21)

21. A tubular intraluminal graft according to claim 19 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering. . .

CLAIMS:

CLMS(22)

22. A tubular intraluminal graft according to claim 21 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(23)

23. A tubular intraluminal graft according to claim 18 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

CLAIMS:

CLMS(24)

24. A tubular intraluminal graft according to claim 23 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(25)

25. A tubular intraluminal graft according to claim 18 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(26)

26. A tubular intraluminal graft according to claim 18 wherein the tubular diametrically adjustable stent is a Nitinol stent.

CLAIMS:

CLMS(27)

27. A tubular intraluminal graft according to claim 18 wherein the stent is a balloon-expandable stent.

CLAIMS:

CLMS(28)

28. A tubular intraluminal graft according to claim 18 wherein the stent is a self-expanding stent of braided wire.

CLAIMS:

CLMS(29)

29. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface, an end edge and a wall, and having a multiplicity of openings through the wall of the stent;
b) a tubular covering of porous expanded polytetrafluoroethylene affixed to the tubular, diametrically adjustable stent, and said tubular covering having an exterior surface, a luminal surface and a seam extending from the exterior surface through. . . covering;
wherein the tubular covering of porous expanded polytetrafluoroethylene is folded over the end edge of the tubular, diametrically adjustable stent and is affixed to the exterior surface and the luminal surface of the tubular diametrically adjustable stent.

CLAIMS:

CLMS(30)

30. A tubular intraluminal graft according to claim 29 wherein the tubular covering is affixed by an adhesive.

CLAIMS:

CLMS(31)

31. A tubular intraluminal graft according to claim 29 wherein the tubular covering is affixed with sutures.

CLAIMS:

CLMS(32)

32. A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) a first tubular covering of porous expanded polytetrafluoroethylene affixed to the exterior surface of the tubular, diametrically adjustable stent; and
c) a second tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent;
wherein the combined thickness of the first and second tubular coverings is less than about 0.10 mm thick exclusive of the stent.

CLAIMS:

CLMS(33)

33. A tubular intraluminal graft according to claim 32 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering of porous expanded polytetrafluoroethylene film through openings through the wall of the stent.

CLAIMS:

CLMS(34)

34. A tubular intraluminal graft according to claim 33 wherein the first tubular covering of porous expanded polytetrafluoroethylene is affixed to the second tubular covering. . .

CLAIMS:

CLMS(35)

35. A tubular intraluminal graft according to claim 34 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(36)

36. A tubular intraluminal graft according to claim 32 wherein the first and second tubular coverings of porous expanded polytetrafluoroethylene are affixed by an adhesive.

CLAIMS:

CLMS(37)

37. A tubular intraluminal graft according to claim 36 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(38)

38. A tubular intraluminal graft according to claim 32 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(39)

39. A tubular intraluminal graft according to claim 33 wherein the first tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented circumferentially with respect to the tubular, diametrically adjustable stent, and wherein the second tubular covering of porous expanded polytetrafluoroethylene has a microstructure of nodes interconnected by uniaxially-oriented fibrils which are oriented longitudinally with respect to the tubular, diametrically adjustable stent.

CLAIMS:

CLMS(40)

40. A tubular intraluminal graft according to claim 32 wherein the tubular diametrically adjustable stent is a Nitinol stent.

CLAIMS:

CLMS(41)

41. A tubular intraluminal graft according to claim 32 wherein the stent is a balloon-expandable stent.

CLAIMS:

CLMS(42)

42. A tubular intraluminal graft according to claim 32 wherein the stent is a self-expanding stent of braided wire.

CLAIMS:

CLMS(43)

43. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) affixing a first tubular covering to the exterior surface and a second tubular covering to the luminal surface, said first. . .

CLAIMS:

CLMS(46)

46. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) affixing a first tubular covering to the exterior surface and a second tubular covering to the luminal surface, and said. . .

US PAT NO: 5,720,776 [IMAGE AVAILABLE] L1: 15 of 37
TITLE: Barb and expandable transluminal graft prosthesis for repair of aneurysm

ABSTRACT:
An . . . the bifurcated lumen of the aorta and the common iliac arteries extending therefrom. The prosthesis assembly includes a single lumen graft or a bifurcated lumen graft having a main body and ipsilateral and contralateral limbs extending therefrom. The main body and ipsilateral and contralateral limbs each have a spring assembly about their orifices for conforming that portion of the graft to the wall of the vessel lumen. The main body spring assembly has an improved barb with first and second. . .

SUMMARY:

BSUM(2)

The invention relates to transluminal graft prostheses for the repair of aneurysms and an improved barb for implanting the prostheses in the vascular system.

SUMMARY:

BSUM(4)

The . . . incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

SUMMARY:

BSUM(5)

Such . . . The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant. . .

SUMMARY:

BSUM(7)

U.S. . . . is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to. . .

SUMMARY:

BSUM(8)

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on. . . to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts. . . repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

SUMMARY:

BSUM(9)

The . . . of Diagnostic Radiology, University of Texas M.D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming. . . compressed radially, and is introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the

catheter while holding the introducer wire stationary. This. . . rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one of these grafts carried barbs. The other model showed. . . a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter.. . .

SUMMARY:

BSUM(10)

Endovascular . . . lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

SUMMARY:

BSUM(11)

The . . . this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY:

BSUM(14)

Still . . . cause the prosthesis assembly to migrate. Such migration can also occur after initial placement due to blood flowing between the graft and vessel wall.

SUMMARY:

BSUM(16)

The . . . and a technical advance is achieved in an improved barb that is employed on the spring assembly of the transluminal graft prosthesis. To minimize, if not completely eliminate, detachment of the barb from the spring assembly, the barb includes a body. . .

SUMMARY:

BSUM(20)

The improved barb is utilized in an improved prosthesis assembly advantageously including a single lumen graft or a bifurcated graft should the prosthesis be needed to support an aneurysm positioned near the bifurcation of the aorta at the ipsilateral and. . .

SUMMARY:

BSUM(21)

The . . . advance is achieved in an improvement to the transluminal arrangement of the present invention. The improvement includes substituting for the stent boot of the transluminal arrangement a sheath having a longitudinal bore that closely approximates the cross-sectional shape of the elongated. . .

SUMMARY:

BSUM(26)

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

SUMMARY:

BSUM(29)

The . . . of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the

longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . .

SUMMARY:

BSUM(30)

The . . . lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . . device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and. . .

SUMMARY:

BSUM(31)

The . . . assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end,. . .

SUMMARY:

BSUM(34)

The . . . and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally. . .

SUMMARY:

BSUM(38)

The . . . the common iliac arteries. A prosthesis assembly for positioning in the aneurysm of the bifurcated lumen includes a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The assembly also includes main and branch limb spring. . . each having a compressed state. The main bore spring assembly radially expands to substantially conform the main body of the graft to the interior wall of the aortal lumen. The ipsilateral and contralateral limb spring assemblies radially expand to conform the limbs of the graft to the interior walls of the branch lumens of the ipsilateral and contralateral iliac arteries. The transluminal arrangement comprises containers. . . the spring assemblies in a compressed state and a retainer assembly positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly at the aneurysm in the bifurcated lumen while the main outer sleeve is withdrawn from. . .

SUMMARY:

BSUM(42)

The . . . when positioned at the aneurysm in the bifurcated lumen allowing the main spring assembly to radially expand and conform the graft to the aorta. The branch limb containers of the transluminal

arrangement are also withdrawn from the branch spring assemblies which then radially expand the ipsilateral and contralateral limbs of the graft to the common iliac arteries so as to advantageously prevent retrograde flow of blood back to the aneurysm. Similarly, the main spring assembly conforms the cranial orifice of the main body of the graft to the wall of the aorta preventing antegrade flow of blood into the aneurysm.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a tubular graft of the instant invention;

DRAWING DESC:

DRWD(7)

FIG. 6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

DRAWING DESC:

DRWD(17)

FIG. 15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

DRAWING DESC:

DRWD(19)

FIG. 18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

DRAWING DESC:

DRWD(21)

FIG. 20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

DRAWING DESC:

DRWD(22)

FIG. 21 depicts a segment of a self-expanding stent;

DRAWING DESC:

DRWD(23)

FIG. 22 depicts a bifurcated graft;

DRAWING DESC:

DRWD(27)

FIG. 28 depicts tubular extensions sutured to a graft of the present invention;

DRAWING DESC:

DRWD(28)

FIG. 29 depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

DRAWING DESC:

DRWD(36)

FIG. 39 depicts a distal stent insertion device of the present invention;

DRAWING DESC:

DRWD(41)

FIG. 44 depicts a partially sectioned side view of ipsilateral limb spring assembly of the prosthesis assembly and stent boot of the transluminal arrangement of FIG. 43;

DRAWING DESC:

DRWD(43)

FIG. 46 depicts a partially sectioned side view of contralateral stent boot temporarily attached to control limb delivery catheter of FIG. 45;

DRAWING DESC:

DRWD(49)

FIG. . . . prosthesis assembly of the present invention with improved barbs on the spring assemblies positioned at opposite ends of the transluminal graft;

DETDESC:

DETD(2)

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron.TM.), which is known to be. . . material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

DETDESC:

DETD(3)

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide. . . a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

DETDESC:

DETD(4)

The . . . apertured 60. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurved arches 42 is that they collapse more readily and are more durable.. . . barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such. . . have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft 1 would be in less intimate contact with the wall of the lumen.

DETDESC:

DETD(5)

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft 1 or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that. . . and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact. . . both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the

graft 1 to provide a more secure anchor in the direction of blood flow. The barbs 10 are positioned so that. . .

DETDESC:

DETD(6)

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to. . . overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has. . .

DETDESC:

DETD(7)

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGS. 9-A and 9-B, the joint is more flexible when the spring assemblies 64. . . d.sub.2). Thus, because .alpha. is larger than .beta., the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

DETDESC:

DETD(10)

FIG. . . . tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath. . .

DETDESC:

DETD(11)

"Muzzle loading" involves inserting the graft 1, already mounted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4. . .

DETDESC:

DETD(12)

"Muzzle . . . loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to. . . totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

DETDESC:

DETD(13)

The . . . over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially. . .

DETDESC:

DETD(14)

FIG. . . . iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted

in the aorta 2 at the site of the aortic aneurysm 20.

DETDESC:

DETD(15)

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled,. . .

DETDESC:

DETD(18)

In . . . into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

DETDESC:

DETD(21)

All . . . devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1 during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including. . . of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially. . .

DETDESC:

DETD(22)

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

DETDESC:

DETD(23)

The . . . of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly. . . tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring. . . means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may. . . 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a. . . of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer. . .

DETDESC:

DETD(24)

FIG. . . . catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

DETDESC:

DETD(25)

These methods of securing the graft to the carrier for selective

release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the. . .

DETDESC:

DETD(26)

The . . . open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy. . . sheath 4 is pulled back exposing the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass. . . tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn. . . and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present). . . past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26,. . .

DETDESC:

DETD(27)

Aortic . . . iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such. . . contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends. . .

DETDESC:

DETD(28)

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

DETDESC:

DETD(30)

When . . . percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

DETDESC:

DETD(31)

Hereinafter described is a bifurcated endovascular graft 150 and the

method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

DETDESC:

DETD(32)

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

DETDESC:

DETD(33)

All . . . the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

DETDESC:

DETD(34)

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251. . .

DETDESC:

DETD(35)

Grafts . . . may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

DETDESC:

DETD(36)

In . . . common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

DETDESC:

DETD(37)

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with. . . fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

DETDESC:

DETD(46)

The . . . control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGS. 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

DETDESC:

DETD(47)

As . . . FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches. . . . suture 252 and 253 that pass along the wall of respective tubular extensions 246 and 247 to the junction with graft 206.

DETDESC:

DETD(48)

Alternatively, ... caudal limb control suture 154 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256. . . . and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when. . . .

DETDESC:

DETD(49)

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter. . . .

DETDESC:

DETD(50)

As . . . . traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216. . . .

DETDESC:

DETD(51)

As . . . . used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 255 is also required on ipsilateral distal limb 213.

DETDESC:

DETD(54)

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

DETDESC:

DETD(55)

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external. . . . sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath.. . . . of the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of caudal stent 275.

DETDESC:

DETD(56)

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. Straightening device 130 is advanced over the distal limb control system onto the end of the distal. . . . of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

DETDESC:

DETD(57)

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132. . . . maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the. . . reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

DETDESC:

DETD(62)

An . . . that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in. . .

DETDESC:

DETD(63)

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method depicted in FIGS. 48 and 49, a Dormier. . .

DETDESC:

DETD(65)

The . . . of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath 217 exposes the caudal limb control mechanisms and their. . . carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral. . .

DETDESC:

DETD(67)

Stents . . . required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used,. . . is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

DETDESC:

DETD(68)

The . . . the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory,. . .

DETDESC:

DETD(70)

Prosthesis assembly 228 depicted in FIG. 43 includes bifurcated endovascular graft 206, main spring assembly 301, and limb spring assemblies 302 and 303 (not shown) positioned in respective stent boots 304 and 305. Main spring assembly 301, as well as prosthesis

assembly 228, is contained in main container sheath 217 which is, for example, a polytetrafluoroethylene tube. Bifurcated endovascular graft 206 includes main body 250 with ipsilateral limb 213 and contralateral limb 210 extending therefrom and partially over the tops of respective stent boots 304 and 305.

DETDESC:

DETD(71)

As . . . through cranial orifice 207 and into bore 251 of the main body for radially expanding the main body of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285. Main spring assembly 301 expands from its compressed state, as shown in. . .

DETDESC:

DETD(72)

Transluminal arrangement 350 includes outer sheath 217 for containing main spring assembly 301 in a compressed state, stent boot sheath 304 for containing ipsilateral spring assembly in a compressed state; stent boot sheath 305 for containing contralateral spring assembly in a compressed state; and main retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining prosthesis assembly 228 in the bifurcated lumen while the outer sheath is withdrawn from the prosthesis assembly releasing. . .

DETDESC:

DETD(75)

FIG. . . . spring assembly is attached to the inside of ipsilateral limb 213 via sutures 315 and 316 and is contained in stent boot sheath 304. When the prosthesis assembly is properly positioned about aneurysm 20, ipsilateral spring assembly 302 is released from. . . state to radially expand limb 213 and substantially conform the limb to the interior wall of common iliac artery 34. Stent boot sheath 304 forms a container for containing ipsilateral spring assembly 302 in a compressed state. Suture 314 is temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in the stent boot sheath during positioning of the prosthesis assembly in the bifurcated lumen. Suture 314 forms a release mechanism for releasing. . . limb 213 is properly positioned in common iliac artery 34. After suture 314 is detached from the ipsilateral spring assembly, stent boot 304 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state, ipsilateral spring assembly 302 radially expands graft limb 213 to substantially conform the limb on an interior wall of iliac artery lumen 286.

DETDESC:

DETD(76)

Stent boot 304 is a tubular container such as a sheath or short piece of polytetrafluoroethylene tube for containing ipsilateral spring assembly 302 therein in a compressed state. Ipsilateral spring assembly 302 is attached along its midsection to contralateral graft limb 213 inside limb bore 253 with sutures 315 and 316. Attachment sutures 315 and 316 are placed cranially from caudal orifice 208 to allow the caudal end of the graft limb to extend over the top of stent boot 304. Attachment sutures 314 and 317 are temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in stent boot 304. One end of attachment sutures 314 and 317 are tied around outer catheter 318 of the transluminal positioning. . . Attachment sutures 314 and 317 and inner catheter 319 form a retainer mechanism for retaining ipsilateral spring assembly 302 in stent boot 304. Connector sleeve 322 is a short length of tubing having apertures 320 and 319 formed laterally therethrough. The. . .

DETDESC:

DETD(77)

FIG. . . . partially sectioned side view of contralateral spring assembly 304, attached to the inside of contralateral limb 210, and contained in stent boot 305. Limb control catheter 255 is attached proximally to stent boot 305 and has suture 254 extending longitudinally through catheter lumen 306. Suture 254 is temporarily attached to contralateral spring assembly for retaining the spring assembly in the stent boot during positioning of the prosthesis assembly in the bifurcated lumen. Suture 254 forms a release mechanism for releasing the. . . contralateral limb 210 is positioned in common iliac artery 35. After suture 254 is detached from the contralateral spring assembly, stent boot 305 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its

compressed state,. . . an interior wall of iliac artery lumen 287. Limb control catheter 255 is a commercially available copolymer tube to which stent boot 305 is integrally formed or attached thereto, for example, using medical grade adhesive. Stent boot 305 is a tubular container such as a short piece of polytetrafluoroethylene tube for containing contralateral spring assembly 303 therein in a compressed state. Contralateral spring assembly 303 is attached along its midsection to contralateral graft limb 210 inside limb bore 255 with sutures 307 and 308. Attachment sutures 307 and 308 are placed cranially from caudal orifice 209 to allow the caudal end of the graft limb to extend over the top of stent boot 305. Contralateral spring assembly 303 can include one or more barbs for digging into the vessel wall and more. . .

DETDESC:

DETD(78)

Depicted . . . arrangement 350 includes a main or outer sheath 217 for containing main spring assembly 301 in a compressed state, a stent boot sheath 304 for containing ipsilateral spring assembly 302 in a compressed state, and stent boot sheath 305 for containing a contralateral spring assembly 303 in a compressed state. The transluminal arrangement also includes retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly in the bifurcated lumen while outer sheath 217 is withdrawn from the prosthesis assembly. As. . . main retainer assembly 351 and in particular elongated member 352 is pulled caudally to release ipsilateral spring assembly 302 from stent boot sheath 304.

DETDESC:

DETD(79)

In order to overcome this problem, the stent boot sheath of the transluminal arrangement has been improved to include tubular sheath 362. The tubular sheath includes a longitudinal. . .

DETDESC:

DETD(83)

FIG. 46 depicts a partially sectioned side view of stent boot 305 attached to control limb delivery catheter 255 which is positioned in longitudinal lumen 311 of contralateral limb straightening device 130. A plurality of longitudinal splines 312 is formed in the proximal end of stent boot 305 to match a corresponding plurality of splines 313 positioned around the distal end of straightening device lumen 311. The mating splines engage each other to rotate the stent boot and contralateral limb for proper positioning within the common iliac artery. Markers are positioned in the graft limbs for radiographic imaging.

DETDESC:

DETD(84)

FIG. . . . 35. Main spring assembly 301 has been released from its compressed state and radially expanded main body 250 of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285 of the aorta. Similarly, ipsilateral spring assembly 302 has been released from its compressed state and elongated member 352 and radially expanded ipsilateral limb 213 of the graft to substantially conform the ipsilateral limb on an interior wall of lumen 286 of common iliac artery 34. Contralateral spring. . . been released from its compressed state and radially expanded contralateral limb 210 to substantially conform the contralateral limb of the graft on an interior wall of lumen 287 of common iliac artery 35. Control limb delivery catheter 255 and stent boot 305 have been withdrawn from the contralateral spring assembly allowing it to expand the contralateral limb of the graft.

DETDESC:

DETD(85)

The . . . sleeve 217 is withdrawn from the prosthesis assembly, and control limb delivery catheter 255 guides the contralateral limb of the graft into branch lumen 287 of iliac artery 35. The attachment sutures are released from the main, ipsilateral and contralateral spring assemblies positioning the prosthesis in the bifurcated lumen. Stent boots 304 and 305 are removed from their respective spring assemblies during withdrawal of retainer assembly 352 and control limb. . .

DETDESC:

DETD(86)

The . . . and that all changes and modifications that come within the scope of the claims are to be protected. In particular, stent boots 304 and 305 have been referred to as containers or sheaths and are typically formed from a thin polytetrafluoroethylene tube of material. The stent boots are either affixed to the outer catheter of the retainer assembly or slidable thereon. Similarly, stent boot 304 is attached using, for example, medical grade adhesive, are slidable at the end of the control delivery catheter.. . . of, for example, a semi-rigid polytetrafluoroethylene material for containing the prosthesis assembly therein. The spring assemblies are of the Gianturco Z-stent type as previously described with or without barbs for more securely affixing the prosthesis assembly to the wall of the bifurcated lumen. Any type of radially expanding spring assembly or stent is contemplated whether the spring assembly or stent is automatically expanded when released from a container or expanded with a dilator balloon and the like.

DETDESC:

DETD(87)

FIG. 53 depicts an improved prosthesis assembly 422 including transluminal graft 1 with upstream and downstream spring assemblies 12 and 31 positioned at opposite ends thereof. Each of the spring assemblies. . .

DETDESC:

DETD(89)

To . . . positioned toward exterior surface 413 of the spring assembly for anchoring in the vessel wall. Since blood flows through the graft from upstream spring assembly 12 to downstream spring assembly 31, first attachment arm 401 includes a hook 408 positioned about. . .

DETDESC:

DETD(91)

To . . . from spring assembly arm 15 to more easily engage the vessel wall and to provide a spacing for inserting the graft material between the second attachment arm and spring assembly arm.

DETDESC:

DETD(97)

Although prosthesis assembly 402 of FIG. 53 has been described as a single lumen graft 1, the prosthesis assembly including the improved barbs can be included in prosthesis assembly 228 with bifurcated graft 206. As previously described, the bifurcated graft includes a cranial spring assembly 301 and first and second caudal spring assemblies 302 and 303. Improved barbs 10 are. . .

CLAIMS:

CLMS(1)

What is claimed is:

1. In a transluminal graft (1; 206) having a spring assembly (12, 31; 301, 302, 303) with a barb (10; 205), an improvement in the. . .

CLAIMS:

CLMS(15)

15. In a transluminal graft (1; 206) having a spring assembly (12, 31; 301, 302, 303) with a barb (10; 205), an improvement in the. . .

CLAIMS:

CLMS(20)

20. A prosthesis assembly (422; 228) comprising:
a transluminal graft (1; 206) having a first (207) and a second end (208, 209) and a passage (251; 252, 253) extending longitudinally therebetween;
a first spring assembly (12; 301) positioned at the first end of the graft and having a first barb (10, 205) wherein the first barb includes a first helical coil (405) having a passage. . . of the first barb are beveled; and
a second spring assembly (31; 302, 303) positioned at the second end of the graft and having a second barb (10; 205); wherein the second barb includes a second helical coil (405) having a passage. . .

US PAT NO: 5,718,973 [IMAGE AVAILABLE] L1: 16 of 37

TITLE: Tubular intraluminal graft

ABSTRACT:
A tubular intraluminal graft for repairing body conduits, made from at least one layer of porous expanded PTFE film that has a microstructure having fibrils oriented in at least two directions which are substantially perpendicular to each other. The tubular intraluminal graft has a wall thickness of less than about 0.25 mm and may have a longitudinally or helically oriented seamline. Additional. . .

SUMMARY:

BSUM(5)

Alternative methods have evolved which use intraluminal vascular grafts in the form of diametrically-expandable metallic stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by. . .

SUMMARY:

BSUM(6)

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

SUMMARY:

BSUM(8)

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at. . . location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of expandable metallic stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

SUMMARY:

BSUM(9)

Intraluminal . . . No. 3,657,744 to Ersek describes a method of using one or more expandable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

SUMMARY:

BSUM(10)

Choudhury, U.S. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terephthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

SUMMARY:

BSUM(11)

Rhodes, . . . sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX.RTM. Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff Ariz.) or Impra.RTM. graft (Impra, Inc. Tempe Ariz.). Both the GORE-TEX Vascular Graft and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra Graft as the sleeve component is that the relatively thick, bulky wall of these extruded, longitudinally expanded PTFE tubes limits the. . . insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of producing an extruded, longitudinally expanded. . .

SUMMARY:

BSUM(13)

The present invention is a tubular intraluminal graft comprised of porous expanded PTFE film having a microstructure of nodes interconnected by fibrils, the fibrils being oriented in at. . .

SUMMARY:

BSUM(16)

Because . . . expanded PTFE films are typically of greatest strength in the directions parallel to the orientation of the fibrils, an intraluminal graft constructed from these multiaxially-oriented porous expanded PTFE films will have good strength characteristics in all directions. The inventive intraluminal graft has a wall with a thickness of less than about 0.25 mm and preferably less than 0.10 mm. The wall of the graft comprises at least one layer of the multiaxially-oriented porous expanded PTFE film.

SUMMARY:

BSUM(17)

The inventive intraluminal graft has good hoop strength because of the multiaxially-oriented film from which it is made. The graft is flexible and collapsible, thereby allowing it to be collapsed to a size much smaller than the full inside diameter. The graft is capable of being implanted into a living body in the collapsed state and can therefore be inserted into a. . . conduit where it is needed with the use of a catheter type of delivery system. One end of the intraluminal graft is then secured by suitable means such as the use of a metallic expandable stent. The use of the inventive intraluminal graft thus allows for the effective repair of living blood vessels without the trauma typically associated with conventional invasive vascular surgery.

SUMMARY:

BSUM(18)

The inventive intraluminal graft may optionally incorporate separate reinforcing ribs intended to serve as additional strength members. The ribs may be either longitudinally oriented or circumferentially oriented as long as they do not prevent the graft from being diametrically collapsed for insertion into the vascular system. These ribs may be in the form of, for example,. . . to about 0.5 mm. The use of, for example, longitudinally-oriented ribs can add significantly to the longitudinal strength of the graft without appreciably interfering with the ability of the graft to be collapsed in diameter for ease of insertion into a vascular system and then subsequently increased in diameter at a different location within the vascular system. These ribs may easily be incorporated into the graft during construction of the graft, for example, by temporarily attaching the ribs to the surface of a manufacturing mandrel prior to wrapping the mandrel with. . . a layer of porous expanded PTFE film. The mandrel assembly can then be heated adequately to cause the ribs to adhere to the film, after which the mandrel can be removed. The ribs may be located on the luminal surface of. . .

DRAWING DESC:

DRWD(2)

FIG. . . . is an enlarged schematic representation of a multiaxially-oriented porous expanded PTFE film having biaxially-oriented fibrils used to construct the intraluminal graft of the present invention.

DRAWING DESC:

DRWD(3)

FIG. . . . is an enlarged schematic representation of a multiaxially-oriented porous expanded PTFE film having multiaxially-oriented fibrils used to construct the intraluminal graft of the present invention.

DRAWING DESC:

DRWD(4)

FIG. . . . a scanning electron photomicrograph .times.500 of a multiaxially-oriented porous expanded PTFE film having biaxially-oriented fibrils used to construct the intraluminal graft of the present invention.

DRAWING DESC:

DRWD(5)

FIG. . . . a scanning electron photomicrograph .times.2000 of a multiaxially-oriented porous expanded PTFE film having multiaxially-oriented fibrils used to construct the intraluminal graft of the present invention.

DRAWING DESC:

DRWD(6)

FIG. 5 is a perspective view of an intraluminal graft of the present invention having a longitudinally oriented seamline.

DRAWING DESC:

DRWD(7)

FIG. 6 is a perspective view of an intraluminal graft of the present invention having a radially oriented seamline.

DRAWING DESC:

DRWD(8)

FIGS. 7A, 7B and 7C are cross sectional views of an intraluminal graft of the present invention made from a single layer of film.

DRAWING DESC:

DRWD(9)

FIG. 8 is a cross sectional view of an intraluminal graft of the present invention made from two layers of film.

DRAWING DESC:

DRWD(10)

FIGS. 9A, 9B and 9C describe cross sectional views of the intraluminal graft incorporating reinforcing ribs.

DRAWING DESC:

DRWD(11)

FIG. 10 describes a perspective view of the intraluminal graft incorporating a reinforcing braid.

DETDESC:

DETD(6)

The tubular intraluminal graft is manufactured by wrapping a multiaxially-oriented porous expanded PTFE film around a mandrel and forming a seamline by overlapping adjacent. . . 5, the seamline 51 may be longitudinally-oriented so that it is substantially parallel to the longitudinal axis 53 of the graft 50. After the seamline 51 is formed, the film-wrapped mandrel is placed into an oven set above the melt-point of the PTFE film 55 for a time adequate to cause the overlapping edges of the film to adhere to each other. After heating, the film-wrapped mandrel is removed from the oven and allowed to cool. The mandrel is then removed from within the resulting tubular intraluminal graft.

DETDESC:

DETD(8)

In . . . of a discontinuous coating in order to have a minimal effect on the porosity of the completed thin wall intraluminal graft. The adhesive must be biocompatible preferred adhesives are thermoplastics of lower melt point than the crystalline melt point of the. . .

DETDESC:

DETD(15)

As described by FIG. 6, the intraluminal graft 50 may be formed by wrapping a tape 61, formed by cutting a multiaxially-oriented porous expanded PTFE film into a narrow strip, helically-wrapping the tape 61 around a mandrel and overlapping adjacent edges of the tape to create a helically-oriented seamline 63. The overlapping adjacent edges may be adhered as described previously for the longitudinally-oriented seamlines 51.

DETDESC:

DETD(16)

FIG. 7A shows a cross section of the intraluminal graft 50 having a simple overlapped seamline 51. In an alternative embodiment described by the cross sectional view of FIG. 7B,. . .

DETDESC:

DETD(17)

As shown by the cross sectional view of FIG. 8, the intraluminal graft may also be made from two or more layers of multiaxially-oriented porous expanded PTFE film by allowing the film to. . .

DETDESC:

DETD(18)

Various samples of the intraluminal graft of the present invention were constructed and are described below as examples. The methods used to characterize the fibril lengths. . .

DETDESC:

DETD(20)

Wall . . . measurements of the finished intraluminal grafts were made by longitudinally slitting the wall of a short length of the tubular graft to create a flat sheet. These wall thickness measurements did not include the overlapped edges of the seamlines. Seamlines are not included in wall thickness measurements unless the width of the seamline is such that the graft is made from two or more layers of film as described by the cross sectional view of FIG. 8. The. . .

DETDESC:

DETD(23)

A . . . porous expanded PTFE film having biaxially-oriented fibrils as described by FIGS. 1 and 3 was used to make an intraluminal graft. The film used was of about 30 micron fibril length, about 10 cm width and about 0.08 mm thickness. A. . . parallel to the circumference of the mandrel and parallel to the longitudinal axis of the mandrel. The film edges were adhered by using a hot iron shielded with a thin sheet of polyimide film. The iron, having a surface temperature of. . . which it was removed from the oven and allowed to cool. The mandrel was then removed from the finished intraluminal graft. A 10 cm length of the intraluminal graft was pressure tested at 1.0 kg/cm.sup.2 for 30 seconds without any adverse visible effects.

DETDESC:

DETD(25)

A length of 12.5 mm wide tape was cut from the same film used to construct Example 1. The strip of tape was cut so that the biaxially-oriented fibrils of the film were oriented substantially parallel and perpendicular to the length of the tape. The tape was then helically wrapped around the surface of a 6 mm stainless steel mandrel as shown by FIG. 6 to form an intraluminal graft of about 16 cm length. Adjacent tape edges overlapped by about 1 mm. The film-wrapped mandrel was then placed into an oven set at 380.degree. C. for. . . 10 minutes after which it was removed and allowed to cool. The mandrel was then removed from the finished intraluminal graft. A 17 cm length of the graft was then pressure tested at 1.0 kg/cm.sup.2 for 3 minutes. The pressure test caused no visible damage to the graft.

DETDESC:

DETD(27)

An intraluminal graft was formed from the film described by FIG. 4. This film had a fibril length of about 5 microns, a. . . was trimmed from the 1 mm wide seamline at this time. The mandrel was then removed from the finished intraluminal graft. A 5 cm length of this graft was then pressure tested at 1.0 kg/cm.sup.2 for 30 seconds without visible damage.

DETDESC:

DETD(28)

As previously described, the intraluminal graft may be provided with longitudinal reinforcing ribs in the form of stringers of, for example, FEP or PTFE. FIG. 9A describes a cross sectional view of an intraluminal graft with ribs 111 on the exterior surface. FIG. 9B describes a

cross sectional view of an intraluminal graft with ribs 111 on the luminal surface. FIG. 9C shows a cross sectional view having ribs 111 between two layers of film. The ribs are not limited to being oriented parallel to the longitudinal axis of the intraluminal graft, but may also be provided to be oriented substantially circumferential to the tube, for example helically oriented. Alternatively, as shown. . .

CLAIMS:

CLMS(1)

We claim:

1. An intraluminal graft comprising a tube having an exterior surface, a luminal surface, ends, and a longitudinal axis, said tube being comprised of. . .

CLAIMS:

CLMS(2)

2. An intraluminal graft according to claim 1 wherein the tube has a seamline formed by overlapping the edges of the porous expanded polytetrafluoroethylene. . .

CLAIMS:

CLMS(3)

3. An intraluminal graft according to claim 2 wherein the seamline is substantially parallel to the longitudinal axis of the tube.

CLAIMS:

CLMS(4)

4. An intraluminal graft according to claim 2 wherein the seamline is helically oriented with respect to the longitudinal axis of the tube.

CLAIMS:

CLMS(5)

5. An intraluminal graft according to claim 1 wherein the tube has a wall thickness of less than about 0.1 mm.

CLAIMS:

CLMS(6)

6. An intraluminal graft according to claim 2 wherein the tube has a wall thickness of less than about 0.1 mm.

CLAIMS:

CLMS(7)

7. An intraluminal graft according to claim 3 wherein the tube has a wall thickness of less than about 0.1 mm.

CLAIMS:

CLMS(8)

8. An intraluminal graft according to claim 4 wherein the tube has a wall thickness of less than about 0.1 mm.

CLAIMS:

CLMS(9)

9. An intraluminal graft according to claim 2 wherein the seamline is adhered by an adhesive.

CLAIMS:

CLMS(10)

10. An intraluminal graft according to claim 9 wherein the adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(11)

11. An intraluminal graft according to claim 1 wherein the tube is provided with at least one reinforcing rib.

CLAIMS:

CLMS(12)

12. An intraluminal graft according to claim 2 wherein the tube is provided with at least one reinforcing rib.

CLAIMS:

CLMS(13)

13. An intraluminal graft according to claim 5 wherein the tube is provided with at least one reinforcing rib.

CLAIMS:

CLMS(14)

14. An intraluminal graft according to claim 6 wherein the tube is provided with at least one reinforcing rib.

CLAIMS:

CLMS(15)

15. An intraluminal graft according to claim 1 wherein the tube is provided with a reinforcing braid.

CLAIMS:

CLMS(16)

16. An intraluminal graft according to claim 2 wherein the tube is provided with a reinforcing braid.

CLAIMS:

CLMS(17)

17. An intraluminal graft according to claim 5 wherein the tube is provided with a reinforcing braid.

CLAIMS:

CLMS(18)

18. An intraluminal graft according to claim 6 wherein the tube is provided with a reinforcing braid.

US PAT NO: 5,700,285 [IMAGE AVAILABLE] L1: 17 of 37
TITLE: Intraluminal stent graft

ABSTRACT:
A tubular intraluminal graft in the form of a tubular diametrically adjustable stent having a tubular covering of porous expanded polytetrafluoroethylene which is less than 0.10 mm thick. The covering may be on the exterior surface of the stent, or on the interior surface of the stent, or both. The covering may be affixed to the stent by an adhesive which is preferably fluorinated ethylene propylene.

SUMMARY:

BSUM(5)

Alternative methods have evolved which use intraluminal vascular grafts in the form of adjustable stent structural supports, tubular grafts or a combination of both. These devices are preferably remotely introduced into a body cavity by. . .

SUMMARY:

BSUM(6)

Intraluminal vascular grafts can also be used to repair aneurysmal vessels, particularly aortic arteries, by inserting an intraluminal vascular graft within the aneurysmal vessel so that the prosthetic withstands the blood pressure forces responsible for creating the aneurysm.

SUMMARY:

BSUM(8)

If the intraluminal graft used is of thin enough wall and adequate flexibility, it may be collapsed and inserted into a body conduit at. .

. location remote from the intended repair site. A catheter type of delivery system is then used to move the intraluminal graft into the repair site and then expand its diameter appropriately to conform to the inner surface of the living vessel. Various attachment methods including the use of adjustable stents may be used to secure the intraluminal graft at the desired location without the necessity of invasive surgery.

SUMMARY:

BSUM(9)

Intraluminal . . . No. 3,657,744 to Ersek describes a method of using one or more adjustable stents to secure a flexible fabric vascular graft intraluminally, the graft and stent having been introduced distally and delivered to the desired position with a separate delivery system.

SUMMARY:

BSUM(10)

Choudhury, U.S. Pat. No. 4,140,126, describes a similar method of repairing aortic aneurysms whereby a polyethylene terphthalate vascular graft is fitted at its ends with metal anchoring pins and pleated longitudinally to collapse the graft to a size small enough to allow for distal introduction.

SUMMARY:

BSUM(11)

Rhodes, . . . sleeve having at least two diametrically-expandable stents. Rhodes teaches that the sleeve material is to be made of conventional vascular graft materials such as GORE-TEX.RTM. Vascular Graft (W. L. Gore & Associates, Inc., Flagstaff Ariz.) or Impra.RTM. Graft (Impra, Inc. Tempe Ariz). Both the GORE-TEX Vascular Graft and Impra Graft are extruded and longitudinally expanded PTFE tubes. Additionally, the GORE-TEX Vascular Graft possesses an exterior helical wrapping of porous expanded PTFE film. The difficulty with the use of either the GORE-TEX Vascular Graft or the Impra graft as the sleeve component is that the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the. . . insertion into a blood vessel. For example, the wall thickness of a 6 mm inside diameter Thin Walled GORE-TEX Vascular Graft is typically 0.4 mm. The thinness of the wall is limited by the difficulty of manufacturing an extruded, longitudinally expanded. . .

SUMMARY:

BSUM(13)

The present invention is a tubular intraluminal graft comprising a tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall having a multiplicity of openings through the wall, and further having a tubular covering of porous expanded PTFE film affixed to the stent, said covering being less than about 0.10 mm thick.

SUMMARY:

BSUM(14)

Porous . . . type as taught by U.S. Pat. No. 4,776,337 which typically require a balloon catheter to increase the diameter of the stent within a blood vessel. The term self-expanding refers to stents which increase in diameter by various other means. Stents of. . .

SUMMARY:

BSUM(15)

The . . . covering of porous expanded PTFE film may be affixed to either the exterior surface or the luminal surface of the stent. Alternatively, a first tubular covering of porous expanded PTFE film may be affixed to the exterior surface of the tubular diametrically adjustable stent and a second tubular covering of porous expanded PTFE film may be affixed to the luminal surface of the tubular diametrically adjustable stent. The first and second tubular coverings of porous expanded PTFE film may be affixed to each other through the openings through the wall of the stent.

SUMMARY:

BSUM(16)

The porous expanded PTFE film may be affixed to the stent with an

adhesive. The adhesive may be a thermoplastic adhesive and more preferably a thermoplastic fluoropolymer adhesive such as fluorinated. . . and second tubular coverings of expanded PTFE film are affixed to each other through the multiplicity of openings in the stent wall, the two coverings may be affixed by heating them above the crystalline melt point of the PTFE film adequately to cause them to thermally adhere, or alternatively they may be affixed by an adhesive such as FEP.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent.

DRAWING DESC:

DRWD(5)

FIG. 4 is a transverse cross section of the stent of Example 1 having a luminal layer of porous expanded PTFE film with longitudinally-oriented fibrils and an exterior layer of. . .

DRAWING DESC:

DRWD(6)

FIG. 5 is a transverse cross section of the stent of Example 2 having a luminal layer of porous expanded PTFE film with biaxially-oriented fibrils.

DRAWING DESC:

DRWD(7)

FIG. 6 is a transverse cross section of the stent of Example 3 having an exterior layer of porous expanded PTFE film with circumferentially-oriented fibrils.

DRAWING DESC:

DRWD(8)

FIG. 7 describes a method of collapsing a previously outwardly adjusted balloon-expandable stent.

DRAWING DESC:

DRWD(9)

FIG. 8 describes the fitting of a single tubular sleeve to both the exterior and luminal surfaces of a stent.

DRAWING DESC:

DRWD(10)

FIG. 9 describes the removal a covered, braided wire stent of the self-expanding type from a manufacturing mandrel by everting the braided wire, thereby placing the covering on the luminal surface of the stent.

DETDESC:

DETD(2)

FIG. 1 is a side view of a typical diametrically adjustable stent. The stent is shown as it would appear implanted into a body conduit with its diameter adjusted beyond the collapsed pre-implantation diameter. While the stent shown is made from metal wire, a perforated sleeve having perforations of suitable shape, size and quantity may also be. . .

DETDESC:

DETD(3)

The stent may be provided with an exterior covering of porous expanded PTFE film, or a luminal covering of porous expanded PTFE. . .

DETDESC:

DETD(6)

Wall thickness measurements of intraluminal graft stent coverings were determined by cutting away a portion of the covering that covered an opening through the stent wall. The thickness of the sample portion was measured by placing the sample portion between the

pads of a Mitutoyo. . .

DETDESC:

DETD(7)

The following examples of intraluminal stent grafts are intended to be illustrative only and are not intended to limit the scope of the invention to only. . .

DETDESC:

DETD(9)

A Nitinol wire stent 10 (Nitinol Medical Technologies, Boston, Mass.) of the type described by FIG. 1 was provided with both a luminal covering and an exterior covering of expanded PTFE film. This 3 cm long stent was formed from 0.25 mm diameter Nitinol wire into a tubular shape of interlocking hexagons. The luminal and exterior coverings. . . to each other. The luminal covering was provided with the fibrils oriented parallel to the longitudinal axis of the tubular stent; the exterior covering was provided with the fibrils oriented substantially circumferential to the tubular stent. The film used for both the luminal and exterior coverings was a porous expanded PTFE film having a discontinuous, porous. . .

DETDESC:

DETD(17)

A . . . axis of the mandrel; the FEP-coated side of the film faced away from the surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped port,on of the mandrel. The 3 cm length of the stent was centered over the 3.0 cm length of film-wrapped mandrel. The stent was then provided with an exterior covering 47 of a 3.0 cm wide tape of the film described above by wrapping the tape circumferentially around the exterior surface of the mandrel so that the edges of the circumferentially-wrapped tape overlapped by about 3 mm to form seam 49. The circumferentially wrapped covering was oriented so that the FEP-coated side of the tape faced inward in contact with the exterior surface of the stent and the outward facing FEP-coated surface of the luminal layer of film exposed through the openings in the stent. Except for the overlapped seam edges 49, the circumferentially-wrapped covering was only one film layer thick. The uniaxially-oriented fibrils of the microstructure of the circumferentially-wrapped tape were circumferentially-oriented about the exterior stent surface.

DETDESC:

DETD(18)

The . . . from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the film-wrapped stent. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause adjacent layers of film to adhere to each other. Thus the luminal layer of film was adhered to the exterior circumferentially wrapped layer through the openings between the adjacent wires of the stent. The combined thickness of the luminal and exterior coverings was about 0.025 mm.

DETDESC:

DETD(19)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(21)

A Nitinol wire stent of the same type used for Example 1 was provided with a luminal covering of a porous expanded PTFE film. . . had a microstructure of uniaxially-oriented fibrils with the fibrils oriented circumferentially about the exterior surface of the mandrel. The Nitinol stent was carefully fitted over the film-wrapped portion of the mandrel. The mandrel assembly yes then placed into an oven set. . . at 360.degree. C. for four minutes. After removal from the oven and subsequent cooling, the mandrel was removed from the stent leaving the wrapped film adhered to the luminal surface of the stent.

This film was then peeled from the luminal stent surface, leaving the FEP-coating and some small shreds of residual porous expanded PTFE adhered to the luminal surface of the stent wires. By removing the film and leaving the FEP adhesive on the luminal stent surface, the film served only as a release substrate for the application of the adhesive to the stent surface.

DETDESC:

DETD(23)

The . . . contacted with the surface of a hand-held iron set at 400.degree. C. to cause the PTFE film seam edges to adhere to each other. Excess material beyond the 2 mm wide seam was trimmed away and discarded. The stent was again carefully fitted over the film-covered mandrel. The resulting assembly was placed into an oven set at 380.degree. C. for three minutes and then removed and allowed to cool, after which the mandrel was removed from the stent. The porous expanded PTFE film appeared to be well adhered to the luminal surface of the wire stent by the FEP coating left from the first, previously removed, layer of film. The wall thickness of the PTFE film. . .

DETDESC:

DETD(24)

The film-covered stent was then chilled in a bath of ice water while being rolled between human fingers applying compression diametrically across the stent. This reduced the outside diameter of the stent to about 0.3 cm. The collapsed stent was then heated by immersion in about 40.degree. C. water, thereby increasing the stent diameter to about 1.5 cm. The film covering showed no visible adverse effects from the process of shrinking and increasing the stent diameter.

DETDESC:

DETD(26)

A Palmaz stent of the balloon-expandable type (part no. PS30, Johnson & Johnson Interventional Systems, Inc., Warren, N.J.) was adjusted from its collapsed. . . 8.0 mm by inserting a tapered stainless steel mandrel followed by a straight 8.0 mm diameter stainless steel mandrel. This stent was then provided with a single layer exterior wrapping of the same discontinuously FEP-coated porous expanded PTFE coating used for the exterior wrapping of the stent of Example 1. This was accomplished by wrapping the film about the exterior surface of the mandrel with the uniaxially-oriented fibrils of the film microstructure oriented parallel to the longitudinal axis of the stent. This exterior covering 61 is described by the transverse cross section of FIG. 6. A 2 mm wide seam 45. . . over these edges and applying heat from a hand-held iron with a surface temperature of about 400.degree. C. The film-wrapped stent 65 was then placed into an oven set at 380.degree. C. for 3 minutes, after which it was removed and allowed to cool. The film appeared to be well adhered to the exterior surface of the stent. The wall thickness of the film covering was about 0.01 mm. The enlarged stent was then collapsed by the following process.

DETDESC:

DETD(27)

A series of 20 cm long 6-0 sutures were tied individually to each of the closed metal stent openings adjacent to one end of a stent. The film-covered stent was provided with a temporary non-adhered additional wrapping of longitudinally-oriented film without FEP and having a microstructure of uniaxially-oriented fibrils. This temporary wrapping was intended as a dry lubricant. As described by FIG. 7 which omits the exterior film covering for clarity, the enlarged stent 71 was then pulled by these sutures 77 through a tapered die 75 of round cross section and 2.5 cm. . . bore at its entrance 78 and a 4.5 mm diameter bore at its exit 79. The result was that the stent was collapsed back to an outside diameter of 4.5 mm. The lubricity of the temporary covering of porous expanded PTFE film aided in making it possible to pull the stent through the die. This temporary covering was removed after completion of the collapsing process. It is anticipated that the use of a tapered die having an appropriately sized, smaller diameter exit bore would result in collapsing the stent to its original collapsed diameter. The film-covered stent was again enlarged to a diameter of 8 mm using a balloon catheter followed by a tapered stainless steel mandrel.. . . The covering of porous expanded PTFE film appeared to be fully intact after the collapsing and enlarging of the film-covered stent.

DETDESC:

DETD(28)

Stent coverings may be affixed to a stent surface by variations on this method. For example, a tubular sleeve may be made from a film of porous expanded PTFE and inverted back into itself and fitted over the inner and outer surfaces of a stent as shown by FIG. 8. The inner 83 and outer 85 portions of the tubular sleeve 81 may be thermally adhered to each other through the openings in the stent wall, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends 87 of the tube together.

DETDESC:

DETD(30)

A . . . single layer, approximate 1 mm overlap covering of porous expanded PTFE film by helically wrapping the wire with a narrow tape cut from a sheet of porous expanded PTFE film. The tape used was 6 mm wide, 0.01 mm thick, 0.3 g/cc density, and had uniaxially-oriented fibrils of about 50 micron fibril length. This tape-covered wire was then heated by pulling the wire through the 0.14 mm diameter orifice of a 2.5 cm long die heated to 400.degree. C., at a rate of 1.5 meters per minute, thereby adhering the overlapped edges of the tape together and thereby adhering the tape to the wire. This wire was then cut into shorter lengths and spooled onto 16 bobbins. These bobbins were used. . .

DETDESC:

DETD(31)

A . . . a braided covering of the above wire was applied at a density of about 16 picks/cm. An additional covering of tape cut from a sheet of porous expanded PTFE film was then helically wrapped over the surface of the wire-braided PTFE mandrel. The tape used for this helical wrapping was of 0.01 mm thickness, 0.3 g/cc density, about 50 micron fibril length and 12. . . C. for four minutes, after which it was removed and allowed to cool. As shown by FIG. 9, the wire-braided stent 91 with the exterior covering of porous expanded PTFE tape was then removed from the non-porous PTFE mandrel 93 by folding the ends 95 of the braided wires back on. . . the braided assembly from the mandrel resulted in the helical wrapping of film being located on the lumen of the stent. This construction offered good self-expanding characteristics in that when longitudinal tension was placed on the stent, the length of the stent increased and the diameter decreased. Upon release of tension, the stent immediately recovered its previous shorter length and larger diameter. This film-covered stent is therefore expected to be useful as a self-expanding stent.

CLAIMS:

CLMS(1)

We claim:

1. A tubular intraluminal graft comprising:
a) a tubular diametrically adjustable stent having an exterior surface, a luminal surface and a wall and having a multiplicity of openings through the wall of the stent;
b) a tubular covering of porous expanded polytetrafluoroethylene affixed to the luminal surface of the tubular, diametrically adjustable stent, said tubular covering being less than about 0.10 mm thick and said tubular covering having an exterior surface, a luminal. . . and a seam extending from the exterior surface, through the luminal surface of the tubular covering; and
wherein said intraluminal graft is adapted for implantation in a body conduit.

CLAIMS:

CLMS(2)

2. A tubular intraluminal graft according to claim 1 wherein the tubular covering of porous expanded polytetrafluoroethylene is affixed to the luminal surface of the tubular diametrically adjustable stent by an adhesive.

CLAIMS:

CLMS(3)

3. A tubular intraluminal graft according to claim 2 wherein the adhesive is a thermoplastic adhesive.

CLAIMS:

CLMS(4)

4. A tubular intraluminal graft according to claim 3 wherein the thermoplastic adhesive is a thermoplastic fluoropolymer adhesive.

CLAIMS:

CLMS(5)

5. A tubular intraluminal graft according to claim 4 wherein the thermoplastic fluoropolymer adhesive is fluorinated ethylene propylene.

CLAIMS:

CLMS(6)

6. A tubular intraluminal graft according to claim 1 wherein the tubular diametrically adjustable stent is a Nitinol stent.

CLAIMS:

CLMS(7)

7. A tubular intraluminal graft according to claim 1 wherein the stent is a balloon-expandable stent.

CLAIMS:

CLMS(8)

8. A tubular intraluminal graft according to claim 1 wherein the stent is a self-expanding stent of braided wire.

CLAIMS:

CLMS(9)

9. A method of making a tubular intraluminal graft comprising:
a) selecting at least one tubular, diametrically adjustable stent having an exterior surface, a luminal surface and a wall, and having a multiplicity of openings through the wall of the stent;
b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent, said covering being less than about 0.10 mm thick and said tubular covering having an exterior surface, a luminal surface. . .

CLAIMS:

CLMS(12)

12. A method of making a tubular intraluminal graft comprising:
a) selecting at least one a tubular diametrically adjustable stent having an exterior surface, a luminal surface and a wall and having a multiplicity of openings through the wall, said tubular diametrically adjustable stent having a collapsed diameter and an enlarged diameter wherein said enlarged diameter is at least 1.5 times the collapsed diameter, wherein said tubular diametrically adjustable stent has been adjusted to the enlarged diameter;
b) affixing a tubular covering to the luminal surface of the tubular, diametrically adjustable stent; c) collapsing the tubular, diametrically adjustable stent to about the collapsed diameter; and wherein said intraluminal graft is adapted for implantation in a body conduit.

US PAT NO: 5,693,084 [IMAGE AVAILABLE] L1: 18 of 37
TITLE: Expandable transluminal graft prosthesis for repair of aneurysm

ABSTRACT:
A . . . the bifurcated lumen of the aorta and the common iliac arteries extending therefrom. The prosthesis assembly includes a bifurcated endovascular graft having a main body and ipsilateral and contralateral limbs extending therefrom. The assembly also includes main, ipsilateral, and contralateral spring assemblies each having a compressed state. When released from its compressed state, each spring expands a portion of the graft to substantially conform that portion of the graft to the wall of the bifurcated lumen. The transluminal arrangement comprises an elongated member extending through the main and ipsilateral bores of the graft and includes attachment sutures and an inner catheter extending therethrough for temporarily attaching the main and ipsilateral spring assemblies to the elongated member. An outer sheath contains the attached prosthesis assembly, whereas stent boots consisting of short length sheaths contain the ipsilateral and contralateral spring assemblies. A control limb delivery catheter and attachment sutures maintain the contralateral graft limb and spring assembly in the stent boot for placement in the contralateral iliac artery.

SUMMARY:

BSUM(2)

The invention relates to transluminal graft prostheses for the repair of aneurysms and a method for implanting them.

SUMMARY:

BSUM(4)

The . . . incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

SUMMARY:

BSUM(5)

Such . . . The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant. . .

SUMMARY:

BSUM(7)

U.S. . . . is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to. . .

SUMMARY:

BSUM(8)

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on. . . to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts. . . repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

SUMMARY:

BSUM(9)

The . . . Diagnostic Radiology, University of Texas M. D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming. . . compressed radially, and is introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the catheter while holding the introducer wire stationary. This. . . rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one

of these grafts carried barbs. The other model showed. . . . a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter.. . .

SUMMARY:

BSUM(10)

Endovascular . . . lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

SUMMARY:

BSUM(11)

The . . . this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY:

BSUM(14)

The . . . advance is achieved in an improvement to the transluminal arrangement of the present invention. The improvement includes substituting for the stent boot of the transluminal arrangement a sheath having a longitudinal bore that closely approximates the cross-sectional shape of the elongated. . . .

SUMMARY:

BSUM(19)

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

SUMMARY:

BSUM(22)

The . . . of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . .

SUMMARY:

BSUM(23)

The . . . lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . . device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and. . .

SUMMARY:

BSUM(24)

The . . . assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end,. . .

SUMMARY:

BSUM(27)

The . . . and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally. . .

SUMMARY:

BSUM(31)

The . . . the common iliac arteries. A prosthesis assembly for positioning in the aneurysm of the bifurcated lumen includes a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The assembly also includes main and branch limb spring. . . each having a compressed state. The main bore spring assembly radially expands to substantially conform the main body of the graft to the interior wall of the aortal lumen. The ipsilateral and contralateral limb spring assemblies radially expand to conform the limbs of the graft to the interior walls of the branch lumens of the ipsilateral and contralateral iliac arteries. The transluminal arrangement comprises containers. . . the spring assemblies in a compressed state and a retainer assembly positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly at the aneurysm in the bifurcated lumen while the main outer sleeve is withdrawn from. . .

SUMMARY:

BSUM(35)

The . . . when positioned at the aneurysm in the bifurcated lumen allowing the main spring assembly to radially expand and conform the graft to the aorta. The branch limb containers of the transluminal arrangement are also withdrawn from the branch spring assemblies which then radially expand the ipsilateral and contralateral limbs of the graft to the common iliac arteries so as to advantageously prevent retrograde flow of blood back to the aneurysm. Similarly, the main spring assembly conforms the cranial orifice of the main body of the graft to the wall of the aorta preventing antegrade flow of blood into the aneurysm.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a tubular graft of the instant invention;

DRAWING DESC:

DRWD(7)

FIG. 6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

DRAWING DESC:

DRWD(17)

FIG. 15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

DRAWING DESC:

DRWD(19)

FIG. 18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

DRAWING DESC:

DRWD(21)

FIG. 20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

DRAWING DESC:

DRWD(22)

FIG. 21 depicts a segment of a self-expanding stent;

DRAWING DESC:

DRWD(23)

FIG. 22 depicts a bifurcated graft;

DRAWING DESC:

DRWD(27)

FIG. 28 depicts tubular extensions sutured to a graft of the present invention;

DRAWING DESC:

DRWD(28)

FIG. 29 depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

DRAWING DESC:

DRWD(36)

FIG. 39 depicts a distal stent insertion device of the present invention;

DRAWING DESC:

DRWD(41)

FIG. 44 depicts a partially sectioned side view of ipsilateral limb spring assembly of the prosthesis assembly and stent boot of the transluminal arrangement of FIG. 43;

DRAWING DESC:

DRWD(43)

FIG. 46 depicts a partially sectioned side view of contralateral stent boot temporarily attached to control limb delivery catheter of FIG.

DETDESC:

DETD(2)

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron.TM.), which is known to be. . . material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

DETDESC:

DETD(3)

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide. . . a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such

material within the main body of the graft.

DETDESC:

DETD(4)

The . . . apertured 60. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurred arches 42 is that they collapse more readily and are more durable.. . . barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such. . . have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft 1 would be in less intimate contact with the wall of the lumen.

DETDESC:

DETD(5)

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft 1 or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that. . . and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact. . . both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the graft 1 to provide a more secure anchor in the direction of blood flow. The barbs 10 are positioned so that. . .

DETDESC:

DETD(6)

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to. . . overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has. . .

DETDESC:

DETD(7)

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGS. 9-A and 9-B, the joint is more flexible when the spring assemblies 64. . . d.sub.2). Thus, because .alpha. is larger than .delta., the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

DETDESC:

DETD(10)

FIG. . . . tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath. . .

DETDESC:

DETD(11)

"Muzzle loading" involves inserting the graft 1, already mounted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4. . .

DETDESC:

DETD(12)

"Muzzle . . . loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of-the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to. . . totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

DETDESC:

DETD(13)

The . . . over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially. . .

DETDESC:

DETD(14)

FIG. . . . iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted in the aorta 2 at the site of the aortic aneurysm 20.

DETDESC:

DETD(15)

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled,. . .

DETDESC:

DETD(18)

In . . . into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

DETDESC:

DETD(21)

All . . . devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1 during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including. . . of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially. . .

DETDESC:

DETD(22)

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

DETDESC:

DETD(23)

The . . . of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly. . . tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring. . . means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may. . . 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a. . . of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer. . .

DETDESC:

DETD(24)

FIG. . . . catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

DETDESC:

DETD(25)

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the. . .

DETDESC:

DETD(26)

The . . . open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy. . . sheath 4 is pulled back exposing the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass. . . tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn. . . and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present). . . past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26,. . .

DETDESC:

DETD(27)

Aortic . . . iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above

the aneurysm, into the iliac artery on the side of insertion. Such. . . contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends. . .

DETDESC:

DETD(28)

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

DETDESC:

DETD(30)

When . . . percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

DETDESC:

DETD(31)

Hereinafter described is a bifurcated endovascular graft 150 and the method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

DETDESC:

DETD(32)

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

DETDESC:

DETD(33)

All . . . the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

DETDESC:

DETD(34)

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251. . .

DETDESC:

DETD(35)

Grafts . . . may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

DETDESC:

DETD(36)

In . . . common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

DETDESC:

DETD(37)

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with. . . fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

DETDESC:

DETD(46)

The . . . control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGS. 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

DETDESC:

DETD(47)

As . . . FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches. . . suture 252 and 253 that pass along the wall of respective tubular extensions 246 and 247 to the junction with graft 206.

DETDESC:

DETD(48)

Alternatively, . . . caudal limb control suture 154 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256. . . and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when. . .

DETDESC:

DETD(49)

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter. . .

DETDESC:

DETD(50)

As . . . traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216. . .

DETDESC:

DETD(51)

As . . . used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 255 is also required on ipsilateral distal limb 213.

DETDESC:

DETD(54)

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

DETDESC:

DETD(55)

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external. . . sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath.. . . of the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of caudal stent 275.

DETDESC:

DETD(56)

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. Straightening device 130 is advanced over the distal limb control system onto the end of the distal. . . of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

DETDESC:

DETD(57)

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132. . . maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the. . . reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

DETDESC:

DETD(62)

An . . . that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in. . .

DETDESC:

DETD(63)

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method depicted in FIGS. 48 and 49, a Dormier. . .

DETDESC:

DETD(65)

The . . . of the anglographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer

sheath 217 exposes the caudal limb control mechanisms and their. . . carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral. . .

DETDESC:

DETD(67)

Stents . . . required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used,. . . is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

DETDESC:

DETD(68)

The . . . the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory,. . .

DETDESC:

DETD(70)

Prosthesis assembly 228 depicted in FIG. 43 includes bifurcated endovascular graft 206, main spring assembly 301, and limb spring assemblies 302 and 303 (not shown) positioned in respective stent boots 304 and 305. Main spring assembly 301, as well as prosthesis assembly 228, is contained in main container sheath 217 which is, for example, a polytetrafluoroethylene tube. Bifurcated endovascular graft 206 includes main body 250 with ipsilateral limb 213 and contralateral limb 210 extending therefrom and partially over the tops of respective stent boots 304 and 305.

DETDESC:

DETD(71)

As . . . through cranial orifice 207 and into bore 251 of the main body for radially expanding the main body of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285. Main spring assembly 301 expands from its compressed state, as shown in. . .

DETDESC:

DETD(72)

Transluminal arrangement 350 includes outer sheath 217 for containing main spring assembly 301 in a compressed state, stent boot sheath 304 for containing ipsilateral spring assembly in a compressed state; stent boot sheath 305 for containing contralateral spring assembly in a compressed state; and main retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining prosthesis assembly 228 in the bifurcated lumen while the outer sheath is withdrawn from the prosthesis assembly releasing. . .

DETDESC:

DETD(75)

FIG. . . . spring assembly is attached to the inside of ipsilateral limb 213 via sutures 315 and 316 and is contained in stent boot sheath 304. When the prosthesis assembly is properly positioned about aneurysm 20, ipsilateral spring assembly 302 is released from. . . state to radially expand limb 213 and substantially conform the limb to the interior wall of common iliac artery 34. Stent boot sheath 304 forms a container for containing ipsilateral spring assembly 302 in a compressed state. Suture 314 is temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in the stent boot sheath during positioning of the prosthesis assembly in the bifurcated lumen. Suture 314 forms a release mechanism for releasing. . . limb 213 is properly positioned in common iliac artery 34. After suture 314 is detached from the ipsilateral spring assembly, stent

boot 304 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state, ipsilateral spring assembly 302 radially expands graft limb 213 to substantially conform the limb on an interior wall of iliac artery lumen 286.

DETDESC:

DETD(76)

Stent boot 304 is a tubular container such as a sheath or short piece of polytetrafluoroethylene tube for containing ipsilateral spring assembly 302 therein in a compressed state. Ipsilateral spring assembly 302 is attached along its midsection to contralateral graft limb 213 inside limb bore 253 with sutures 315 and 316. Attachment sutures 315 and 316 are placed cranially from caudal orifice 208 to allow the caudal end of the graft limb to extend over the top of stent boot 304. Attachment sutures 314 and 317 are temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in stent boot 304. One end of attachment sutures 314 and 317 are tied around outer catheter 318 of the transluminal positioning. . . Attachment sutures 314 and 317 and inner catheter 319 form a retainer mechanism for retaining ipsilateral spring assembly 302 in stent boot 304. Connector sleeve 322 is a short length of tubing having apertures 320 and 319 formed laterally therethrough. The. . .

DETDESC:

DETD(77)

FIG. . . . partially sectioned side view of contralateral spring assembly 304, attached to the inside of contralateral limb 210, and contained in stent boot 305. Limb control catheter 255 is attached proximally to stent boot 305 and has suture 254 extending longitudinally through catheter lumen 306. Suture 254 is temporarily attached to contralateral spring assembly for retaining the spring assembly in the stent boot during positioning of the prosthesis assembly in the bifurcated lumen. Suture 254 forms a release mechanism for releasing the. . . contralateral limb 210 is positioned in common iliac artery 35. After suture 254 is detached from the contralateral spring assembly, stent boot 305 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state,. . . an interior wall of iliac artery lumen 287. Limb control catheter 255 is a commercially available copolymer tube to which stent boot 305 is integrally formed or attached thereto, for example, using medical grade adhesive. Stent boot 305 is a tubular container such as a short piece of polytetrafluoroethylene tube for containing contralateral spring assembly 303 therein in a compressed state. Contralateral spring assembly 303 is attached along its midsection to contralateral graft limb 210 inside limb bore 255 with sutures 307 and 308. Attachment sutures 307 and 308 are placed cranially from caudal orifice 209 to allow the caudal end of the graft limb to extend over the top of stent boot 305. Contralateral spring assembly 303 can include one or more barbs for digging into the vessel wall and more. . .

DETDESC:

DETD(78)

Depicted . . . arrangement 350 includes a main or outer sheath 217 for containing main spring assembly 301 in a compressed state, a stent boot sheath 304 for containing ipsilateral spring assembly 302 in a compressed state, and stent boot sheath 305 for containing a contralateral spring assembly 303 in a compressed state. The transluminal arrangement also includes main retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly in the bifurcated lumen while outer sheath 217 is withdrawn from the prosthesis assembly. As. . . main retainer assembly 351 and, in particular, elongated member 352 is pulled caudally to release ipsilateral spring assembly 302 from stent boot sheath 304.

DETDESC:

DETD(79)

In order to overcome this problem, the stent boot sheath of the transluminal arrangement has been improved to include tubular sheath 362. The tubular sheath includes a longitudinal. . .

DETDESC:

DETD(83)

FIG. 46 depicts a partially sectioned side view of stent boot 305 attached to control limb delivery catheter 255 which is positioned in longitudinal lumen 311 of contralateral limb straightening device 130. A plurality of longitudinal splines 312 is formed in the proximal end of

stent boot 305 to match a corresponding plurality of splines 313 positioned around the distal end of straightening device lumen 311. The mating splines engage each other to rotate the stent boot and contralateral limb for proper positioning within the common iliac artery. Markers are positioned in the graft limbs for radiographic imaging.

DETDESC:

DETD(84)

FIG. . . . 35. Main spring assembly 301 has been released from its compressed state and radially expanded main body 250 of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285 of the aorta. Similarly, ipsilateral spring assembly 302 has been released from its compressed state and elongated member 352 and radially expanded ipsilateral limb 213 of the graft to substantially conform the ipsilateral limb on an interior wall of lumen 286 of common iliac artery 34. Contralateral spring. . . been released from its compressed state and radially expanded contralateral limb 210 to substantially conform the contralateral limb of the graft on an interior wall of lumen 287 of common iliac artery 35. Control limb delivery catheter 255 and stent boot 305 have been withdrawn from the contralateral spring assembly allowing it to expand the contralateral limb of the graft.

DETDESC:

DETD(85)

The . . . sleeve 217 is withdrawn from the prosthesis assembly, and control limb delivery catheter 255 guides the contralateral limb of the graft into branch lumen 287 of iliac artery 35. The attachment sutures are released from the main, ipsilateral and contralateral spring assemblies positioning the prosthesis in the bifurcated lumen. Stent boots 304 and 305 are removed from their respective spring assemblies during withdrawal of retainer assembly 352 and control limb. . .

DETDESC:

DETD(86)

The . . . and that all changes and modifications that come within the scope of the claims are to be protected. In particular, stent boots 304 and 305 have been referred to as containers or sheaths and are typically formed from a thin polytetrafluoroethylene tube of material. The stent boots are either affixed to the outer catheter of the retainer assembly or slidable thereon. Similarly, stent boot 304 is attached using, for example, medical grade adhesive, are slidable at the end of the control delivery catheter.. . . of, for example, a semi-rigid polytetrafluoroethylene material for containing the prosthesis assembly therein. The spring assemblies are of the Gianturco Z-stent type as previously described with or without barbs for more securely affixing the prosthesis assembly to the wall of the bifurcated lumen. Any type of radially expanding spring assembly or stent is contemplated whether the spring assembly or stent is automatically expanded when released from a container or expanded with a dilator balloon and the like.

CLAIMS:

CLMS(1)

What . . .

a main sheath (217) having a longitudinal bore (359) and being adapted to position a prosthesis assembly (228) therein; a stent boot (304); and an elongated member (352) having a cross-sectional shape and positioned in the boot (304) and in the. . .

CLAIMS:

CLMS(7)

7. . . . a main sheath (217) having a longitudinal bore (359) and being adapted to position a prosthesis assembly (228) therein; a stent boot (304); and an elongated member (352) having a cross-sectional shape and positioned in the boot (304) and in the. . .

CLAIMS:

CLMS(17)

17. . . . a main sheath (217) having a longitudinal bore (359) and being adapted to position a prosthesis assembly (228) therein; a stent boot (304); an elongated cylindrical member (352) positioned through the boot and in the bore of the main sheath, an. . .

US PAT NO: 5,662,712 [IMAGE AVAILABLE] L1: 19 of 37

SUMMARY:

BSUM(7)

Typically, . . . fluid. In that method, heat is conducted from the fluid in the balloon, through the balloon material, and into the stent. Since conduction is a relatively slow process and the balloon has a relative large thermal mass, energy is transferred not only to the stent, but also to the surrounding body tissues and fluids. The result is that undesired amounts of heat are transferred into. . .

SUMMARY:

BSUM(12)

The resulting shaped article provides a therapeutic benefit by acting, in one embodiment, as a stent to maintain patency through a blood vessel. Numerous other therapeutic shapes are contemplated as well.

DETDESC:

DETD(36)
G. Polyoryalkylenes, where alkene is 1 to 4 carbons, as homopolymers and copolymers including graft copolymers.

DETDESC:

DETD(56)

In one embodiment, the polymeric material may comprise a stent that is applied to the interior of a blood vessel following treatment of a stenosis by angioplasty. In that embodiment,. . .

DETDESC:

DETD(89)

The . . . is guided to a treatment location. Alternatively, other mechanical means such as end caps, or other retainers known in the stent art may be used to retain the article on the balloon. In particular, retaining sleeves or grommets of silicone or. . .

DETDESC:

DETD(107)

For . . . foreign material (i.e., polymer) placed into the blood vessel. Perforations may encourage more rapid and complete encapsulation of the polymeric stent, which may be desired to prevent distal embolization.

DETDESC:

DETD(108)

The . . . surfaces to prevent the formation of connective tissue following trauma or surgical injury, or the material may be used to adhere tissue surfaces to other tissues or implants. In one embodiment, the adherent properties of the materials may be used to join severed nerve endings. These and other applications are described in detail. . .

DETDESC:

DETD(131)

Devices, . . . (1050 micron) mandrel to obtain a roll about 10 mm long along the mandrel. The roll was secured with Teflon tape and heat set at 50 degrees C. at least 12 hours. The rolled devices were cold sterilized with ethylene oxide. . .

US PAT NO: 5,639,278 [IMAGE AVAILABLE] L1: 20 of 37

ABSTRACT:
An endoluminal graft which is both expandable and supportive is provided in a form suitable for use in a bifurcated body vessel location. The graft expands between a first diameter and a second, larger diameter. The support component is an expandable stent endoprosthesis. A cover, a liner, or both a cover and a liner are applied to the endoprosthesis in the form. . . porous, elastomeric and biocompatible in order to allow normal cellular invasion upon implantation, without stenosis, when the expandable and supportive graft is at its second diameter. The supportive endoluminal graft is preferably provided as a plurality of components that are deployed separately at the bifurcated body vessel location.

SUMMARY:

BSUM(2)

This . . . relates to supportive endoluminal grafts which have the ability to be delivered transluminally and expanded in place to provide a graft that is endoluminally positioned and placed, with the aid of an appropriate inserter or catheter, and that remains so placed in order to both repair a vessel defect and provide lasting support at the location of the graft. In its broadest sense, the graft combines into a single structure both an expandable luminal prosthesis tubular support component and an elastomeric graft component secured thereto. The expandable supportive luminal graft takes on a bifurcated structure made up of components that are designed to be positioned in a bifurcated manner with. . . respect to each other during deployment or repair and support of vessel locations at or near branching sites. Preferably, the graft component is stretchable or elastomeric and does not substantially inhibit expansion of the tubular support component while simultaneously exhibiting porosity. . .

SUMMARY:

BSUM(4)

Also known are stent devices, which are placed or implanted within a blood vessel or other body cavity or vessel for treating occlusions, stenoses,. . .

SUMMARY:

BSUM(5)

One common procedure for implanting a stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the diseased portion of the vessel. Various constructions and designs of stents are known. U.S. Pat. No. 4,140,126 describes a technique for positioning an elongated cylindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall, the stent being a cylinder that expands to an implanted configuration after insertion with the aid of a catheter. Other such devices. . . spring to expand. Spring-into-place stents are shown in U.S. Pat. No. 4,580,568. U.S. Pat. No. 4,733,665 shows a number of stent configurations for implantation with the aid of a balloon catheter. U.S. Pat. No. 5,019,090 shows a generally cylindrical stent formed from a wire that is bent into a series of tight turns and then spirally wound about a cylindrical mandrel to form the stent. When radially outwardly directed forces are applied to the stent, such as by the balloon of an angioplasty catheter, the sharp bends open up and the stent diameter enlarges. U.S. Pat. No. 4,994,071 describes a bifurcating stent having a plurality of wire loops that are interconnected by an elongated wire backbone and/or by wire connections and half. . .

SUMMARY:

BSUM(6)

Stents themselves often do not encourage normal cellular invasion and can lead to undisciplined development of cells in the stent mesh, with rapid development of cellular hyperplasia. Grafts alone do not provide adequate support in certain instances. Copending application of Jean-Pierre Dereume, Ser. No. 112,774, entitled "Luminal Graft Endoprostheses and Manufacture Thereof" describes grafts that have the ability to carry out dilatation and/or support functions. An expandable tubular support component and an elastomeric graft component are combined into a single device wherein the graft material is secured to either or both of the internal and external surfaces of the expandable support component. The graft material is produced by a spinning technique such as that described in U.S. Pat. No. 4,475,972. Also, luminal endoprostheses with. . . Surgical Research, 40, 305-309, 1986, and U.S. Pat. No. 5,019,090 and U.S. Pat. No. 5,092,877 mention the possibility to coat stent materials with porous or textured surfaces for cellular ingrowth or with non-thrombogenic agents and/or drugs. The various patents and publications. . .

SUMMARY:

BSUM(7)

By . . . to a second diameter which is greater than the first. When it is at its first diameter, the expandable supportive graft is of a size and shape suitable for insertion into the desired body passageway. The material of the graft is substantially inert and has a generally cylindrical cover and/or lining generally over the outside and/or inside surface of the. . . up to about 2 to 4 times or more of its unexpanded diameter. Components of the bifurcated expandable supportive luminal

graft are deployable separately such that each component is properly positioned with respect to the other into the desired bifurcated arrangement.

SUMMARY:

BSUM(8)

It is a general object of the present invention to provide an improved endoluminal graft that is expandable in place and, once expanded, is self-supporting.

SUMMARY:

BSUM(10)

Another object of the present invention is to provide an improved expandable reinforced graft that is delivered by way of introducers, balloon catheters or similar devices, and which facilitates good tissue ingrowth.

SUMMARY:

BSUM(11)

Another object of this invention is to provide an improved endoluminal graft which fully covers diseased or damaged areas for carrying out luminal repairs or treatments, such as repair of aneurysms.

SUMMARY:

BSUM(12)

Another object of the present invention is to provide an improved endoluminal graft wherein the endoprosthesis is substantially enclosed within biocompatible elastomeric material which is presented to the surrounding tissue and blood or. . .

SUMMARY:

BSUM(13)

Another object of this invention is to provide an expandable, supportive graft that can be tailored to meet a variety of needs, including a single graft designed to address more than a single objective.

SUMMARY:

BSUM(14)

Another object of the present invention is to provide a self-expanding reinforced graft device that is delivered in its elongated and compressed state from within a tubular member and deployed by moving same. . .

SUMMARY:

BSUM(16)

A further object of the present invention is to provide a component bifurcated endoluminal graft having a bifurcated trunk and at least one cylindrical branch which are expanded separately after endoluminal delivery and such that they form a bifurcated graft once positioned with respect to each other and expanded, typically separately.

DRAWING DESC:

DRWD(3)

FIG. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction in accordance with the invention;

DRAWING DESC:

DRWD(5)

FIG. 3 is a perspective view, partially cut away, of another embodiment of the expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(7)

FIG. 5 is a perspective view, partially cut away, of a further embodiment of the expandable luminal graft construction;

DRAWING DESC:

DRWD(9)

FIG. 7 is a perspective view, partially cut away, of a bifurcated expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(13)

FIG. 13 shows this bifurcated supportive graft after completion of the expansion procedure;

DRAWING DESC:

DRWD(14)

FIG. 14 illustrates another embodiment of a bifurcated expandable supportive endoluminal graft construction;

DRAWING DESC:

DRWD(15)

FIGS. 15, 16 and 17 illustrate implantation and assembly of the graft of FIG. 14;

DRAWING DESC:

DRWD(16)

FIGS. 18, 19, 20, 21, 22, 23, 24 and 25 illustrate a component bifurcated graft and various stages of its separate, component deployment within the body vessel to repair an aneurysm, FIGS. 18 and 19. . .

DETDESC:

DETD(2)

An embodiment of expandable supportive luminal graft construction is generally illustrated in FIG. 1 at 21. This embodiment includes a braided tubular support component having generally helically. . .

DETDESC:

DETD(4)

Liner . . . in FIGS. 18, 20 and 23) is used to prevent automatic radial expansion prior to deployment. When the expandable supportive graft 21 is to include a cover 23, the mandrel is again rotated, and the electrostatic spinning is again accomplished in. . . sponge such that the still tacky outer fibers bond to the inner fibers thereby encapsulating the tubular support within the graft.

DETDESC:

DETD(6)

It . . . both are present, is made of an elastomeric material which retains its compliant properties after construction of the expandable supportive graft 21 is completed. In this regard, the graft itself is also elastomeric and compliant. Accordingly, the graft 21 is delivered transluminally, such as by being pulled down onto the balloon of a catheter and then percutaneously inserted and positioned to the location where the repair is needed. For a non-spring loaded graft, the balloon is then inflated to longitudinally contract and radially expand the graft 21 into engagement with the vessel walls. Because of the compliance of the cover 23 and/or liner 24, and because of the hoop strength of the braided tubular support 22, the graft 21 will remain in place. In the illustrated embodiment, ends 25 of the tubular support are exposed and are not. . . 25 to directly engage the vessel wall, if desired in the particular application, in order to assist in anchoring the graft 21 in place. Liner 24 also can be sized so as to not cover the exposed ends 25, or it. . .

DETDESC:

DETD(7)

Alternatively, when a braided tubular support such as that illustrated in FIGS. 1 and 2 is incorporated into the graft according to the present invention in a non-spring-loaded form, transluminal delivery can be made by way of a catheter or. . . other in order to thereby longitudinally compress the endoprosthesis. Delivery tools for spring-loaded grafts include a sleeve that maintains the graft at its

compressed diameter until the graft is positioned for deployment such as from the end of an insertion catheter to its auto-expanded state.

DETDESC:

DETD(8)

With reference to the embodiment illustrated in FIGS. 3 and 4, an expandable supportive graft is illustrated at 31. The illustrated tubular support component 32 is constructed of sinusoidally configured wire helically wound into a. . . as a percent by volume of a pre-elution mixture thereof with the polymer of the cover or liner. When a graft 31 having both a cover 33 and a liner 34 is prepared, a mandrel or rod is dipped into a. . .

DETDESC:

DETD(10)

As . . . particular repair or treatment to be carried out. With this approach, the exposed ends 35 will assist in maintaining the graft 32 in place by mechanical engagement between the exposed ends 35 and the vessel being repaired or treated and/or by. . . exposed ends to expand radially outwardly in an amount somewhat greater than that of the rest of the expandable supportive graft and into the surrounding tissue. It is also contemplated that mechanical means can be used to assist in joining the. . . Illustrated staples are shown at 36 in FIG. 3. They can be incorporated at other locations as well along the graft. One or more windows 37 can be formed through the cover and/or liner and/or tubular support in order to feed. . .

DETDESC:

DETD(11)

FIGS. 5 and 6 illustrate a further embodiment of an expandable supported graft, generally designated as 41. Shown is a mesh tubular support component, generally designated as 42, such as those of the. . .

DETDESC:

DETD(14)

FIGS. 7 and 8 illustrate an embodiment wherein the graft takes the form of a bifurcated expandable supportive graft, generally designated at 51. Included is a joined-ring bifurcated tubular support 52. Also shown are a bifurcated cover 53, a bifurcated lining 54 and exposed ends 55, 56, 57. This particular bifurcating graft is well-suited for insertion into a branching vessel.

DETDESC:

DETD(17)

With . . . the cover and/or liner. In an especially advantageous arrangement when using these fiber spinning techniques in forming an expandable supportive graft in accordance with the general aspects of this invention which has both a liner and a cover, the cover is. . .

DETDESC:

DETD(18)

With . . . bifurcating vessel, each of them into different legs 66, 67 of the bifurcating vessel. Thereafter, the unexpanded bifurcated expandable supportive graft 51 is slipped over the proximal ends of the guidewires and routed to the branches of the blood vessel. The unexpanded bifurcated graft can be introduced from an arteriotomy proximal to the bifurcation such as from the brachial artery in the arm, or the unexpanded bifurcated graft can be introduced from the femoral artery in the leg, pushed proximally past the bifurcation and then pulled back distally. . .

DETDESC:

DETD(19)

The two branches 62, 63 of the graft 51 are routed separately over the guidewires 64, 65, respectively, and guided, typically with the help of a guide catheter, into the patient until the graft is positioned as shown in FIG. 9. The graft 51 is initially fixed in place as follows. One of the guidewires 65 is removed, and a balloon catheter 68. . . and inflated to expand the trunk 61 into contact with the vessel walls. This deployment is suitable to secure the graft 51 in place at that location of the vessel.

DETDESC:

DETD(20)

The . . . is then deflated. If this balloon catheter is also suitable for use in expanding the branches 62, 63 of the graft 51, same is then inserted into an unexpanded branch 62 and radially expanded as generally shown in FIG. 11. If. . . regard, then another balloon catheter 69 effects this function. FIG. 12 shows inflation of the other branch 63 of the graft 51 in a similar manner. FIG. 13 illustrates the fully deployed and expanded bifurcated support graft 51 positioned in place within the bifurcated location. Alternatively, a bifurcated dilation balloon on a bifurcated catheter (not shown) can. . .

DETDESC:

DETD(21)

When the bifurcated expandable supportive graft is of a spring-into-place type, same will be placed within an overlying and bifurcated restraining guiding catheter or the like. . . guidewires and contained within the guiding catheter until proper placement within the bifurcating location. This type of bifurcated expandable supportive graft is deployed by being ejected into place by advancing a small inner catheter through the guiding catheter into contact with the bifurcating graft in accordance with the procedure generally used for spring-into-place stents.

DETDESC:

DETD(22)

The . . . illustrated in FIGS. 9 through 13 can be characterized as prograde deployment. Retrograde deployment is also possible. The entire bifurcating graft for retrograde deployment is advanced over a single guidewire through one branch of the blood vessel past the point of bifurcation. A second guidewire is then steered down the opposite limb of the graft, and a snare is used. The snare, which is passed retrograde through the opposite vessel, is then used to pull. . . place. Partial balloon inflation in the unbranched or trunk portion of the blood vessel is then used to draw the graft down into position prior to balloon dilatation of both the trunk and branched portions of the graft. Because blood flow is prograde under these circumstances, the contact between the bifurcation of the graft and the bifurcation of the blood vessel helps to prevent the graft from migrating distally, thus reducing the need for active fixation of the graft to the blood vessel.

DETDESC:

DETD(23)

Another bifurcated endoprosthesis or expandable supportive graft is generally designated 81 in FIG. 14. Separate components are included. In this case tubular supporting component(s) are, prior to. . . trunk component. In this embodiment, a fully independent tubular supporting component 82 is located at the trunk position of the graft 81. A bifurcated stretchable wall 83 is in contact with the independent tubular supporting component 82 as either or both. . .

DETDESC:

DETD(24)

Implantation of this bifurcated expandable supportive graft is depicted in FIGS. 14, 15, 16 and 17. Dual guidewires 64, 65 can be used to properly position the unexpanded bifurcated graft 81 within the bifurcating vessel as shown in FIG. 14. A balloon catheter 68 or similarly functioning device is inserted. . . component 82 and the trunk portion 84 of the bifurcated stretchable wall 83. This deployment initially secures the bifurcated supporting graft into place at that location of the vessel, as shown in FIG. 15. The balloon catheter is then deflated and. . .

DETDESC:

DETD(26)

A further bifurcated endoprosthesis or expandable supportive graft is one in which the separate components are each expandable supportive graft members. These separate components are illustrated in FIG. 18 through FIG. 24, which also illustrate their separate deployment with respect. . . be made longer so that it extends closer to the aorto-iliac bifurcation site. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means an introducer containing compressed expandable supportive graft components.

DETDESC:

DETD(28)

FIG. 20 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (FIG. 21) radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg. . . deployed trunk component 101. This positioning is illustrated in FIG. 21. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery. . .

DETDESC:

DETD(29)

In . . . generally designated as 114 is advanced over the guidewire 111 and into leg 113. Introducer 114 contains another tubular supportive graft leg component 115 (FIG. 24), which is another iliac component. With the introducer 14 removed, the previously radially compressed iliac component 115 expands radially and is deployed. At this stage, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together.

DETDESC:

DETD(31)

It . . . of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs,. . .

DETDESC:

DETD(32)

FIG. . . . bifurcated portion, generally designated as 119. The bifurcated portion includes the legs 109 and 113. Trunk component 101a includes a stent or tubular supporting component 121, as perhaps best seen in FIG. 27. Also included is a liner, generally designated as. . .

DETDESC:

DETD(33)

Each leg 109, 113 is secured to the generally tubular stent component 121 at outside portions thereof, particularly at adhesion zones 124 and 125. The remainder of the leg portions 109 and 113 are not so bonded to the stent portion 121. This facilitates formation of the leg portions, which are typically pinched along the length of the legs in. . .

DETDESC:

DETD(34)

In FIG. 28, means are included in the trunk component 101b which provides enhanced securement upon implantation. A stent component 129 is included which has a substantially higher pitch angle (for example, between about 140.degree. and 180.degree.) than does the stent portion 121b therebelow within which the legs are positioned (for example, at a pitch angle of between about 70.degree. and 90.degree.). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121 of the trunk component 101a. A barb 130 is also shown in order to further assist in securement of. . . the artery wall. When desired, the barb-type of structure can be a backing ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

DETDESC:

DETD(35)

Any of the various expandable supportive endoluminal graft, or stent graft, constructions discussed or referred to herein can be used in order to construct devices in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable. . . devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a

portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such. . .

DETDESC:

DETD(37)

It . . . defects or diseased areas, including at or in proximity to sites of vascular bifurcations, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the grafts interface with body components that facilitate normal cellular invasion without stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially. . .

DETDESC:

DETD(38)

In . . . be totally inert. Any of a variety of these endoprostheses can be combined with any of a variety of the graft cover and/or liner configurations in order to tailor the expandable supportive graft to meet specific needs. Also, combinations can be obtained, such as providing phase inversion pores and salt elution pores on different locations of the graft component to take advantage of the pore size difference between these two types of graft techniques and/or to provide better tissue growth at one location than at another.

DETDESC:

DETD(40)

In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more biocompatible. Included are the use of pyrolytic carbon, hydrogels and the like. The surface treatments can also provide for. . .

DETDESC:

DETD(41)

The expandable supportive graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or disease. . . the anatomy of the vessel. For example, it can be desirable to have the support component of the expandable supportive graft at locations other than throughout the entirety of the graft as specifically illustrated in FIGS. 1 through 4 hereof. The bifurcated graft of FIGS. 7 and 8 shows some separation along the support component, such as between the trunk 61 and the. . . branches 62, 63. It is also possible, with the grafts in accordance with the present invention, to provide an expandable graft having its supportive property emanating from one or more support components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a support component which can be presented at one end, both ends, or spaced along the expandable supportive graft in accordance with invention.

DETDESC:

DETD(42)

Such a structure is generally illustrated in FIG. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first support component 72 and another or second support component 73. The expandable supportive graft in accordance with the present invention provides the tailorability advantage of being able to vary within a single graft the configuration, structure and properties of the support component or components of the graft. These various properties allow the expandable supportive graft to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support may. . . location being treated, while a less rigid supportive area is needed at another, generally adjoining location. By the expandable supportive graft in accordance with this invention, a single graft can be deployed in order to effect two or more different functions. By achieving multiple support and/or repair functions with. . .

DETDESC:

DETD(43)

With . . . dissection with or without intimal flaps, thrombosis,

embolism, and the like. Another suitable use is for dilating and/or supporting vascular graft bifurcations and the like. Additionally, lesions affecting vascular trifurcations can be treated. Also treatable are obstructed openings characterized by exaggerated. . .

DETDESC:

DETD(44)

It is also desirable to incorporate a radiopaque marker in the endoluminal graft specifically in the area of the trunk defining the bifurcation. The purpose of the marker is to allow one well. . . silicone rubber, polyurethane, epoxy and the like, wherein the binder containing the metal powder is painted or printed onto the graft in the desired location. Alternatively, radiopaque sutures or wires can be sewn into the graft at the bifurcation to allow visualization of the device. Similarly, the proximal ends of the leg endoluminal grafts can be. . .

DETDESC:

DETD(46)

A vascular expandable supportive endoluminal graft was made using a 16 mm diameter, 12 cm long Wallstent.RTM. device as the support component in the following manner.. . . an additional 3 hours at 110.degree. C., after which the assembly was removed from the mandrel. The expandable supportive endoluminal graft formed in this manner had the bulk of the urethane mesh on the inside of the stent. This endoprosthesis is suitable for repairing aortic aneurysms.

DETDESC:

DETD(48)

A bifurcated aortic expandable supportive endoluminal graft is made in the following manner. An aortic trunk supportive endoluminal graft is fabricated using a 16 mm diameter, 12 cm long support component. First, a 16 mm mandrel is rotated on. . . for an additional 3 hours at 110.degree. C., after which the assembly was removed from the mandrel. The supportive endoluminal graft formed in this manner has fiber diameters of 10 to 20.mu. and pore sizes ranging from 10 to 60.mu.. The. . .

DETDESC:

DETD(50)

A bifurcated expandable supportive endoluminal graft is provided for deployment within and repair of aorto-iliac aneurysms. A generally tubular metallic stent of the self-expandable type is adhered to the outside of a porous spun liner as follows. The graft is wound or spun from filaments deposited onto a rotating mandrel in order to form a cylindrical graft having crossing strands generally adhered together. The resulting inner liner, after it is dried, has a stent component placed over it. Then, an area of the stent is masked, such as with a piece of tape, at the location where an internal seam is to be positioned in the trunk component of the supportive endoluminal graft. The masking can take on a shape on the order of the triangular areas illustrated in FIG. 27, with the upper apex forming the "crotch" of the "pants". Additional fibers are then spun over the entire stent and pressed through the stent intersticies to be certain that the stent is secured to the liner. This continues until all areas of the stent are well-bonded except for the masked area. After removal of the mandrel and of the masking material, the initially formed inner liner is free to be pinched along its length and sutured, sewed and/or glued and the like to form two distinct leg portions and a trunk portion of the liner. The resulting trunk component. . .

DETDESC:

DETD(51)

The leg components of the bifurcated expandable supportive endoluminal graft in accordance with this Example are individually made in a similar manner. The liner is formed by spinning compliant fibers over a rotating mandrel, a tubular stent component is positioned thereover and secured in place, and additional fibers are wound with the rotating mandrel. The stent is thus encapsulated between the liner fibers and the cover fibers, preferably with the aid of a soft roller or sponge to force the cover strands into the intersticies of the stent component and securement to the underlying liner fibers. After removal from the mandrel, the resulting tubular supported graft component, suitable for use as both the iliac components, is trimmed to proper length.

CLAIMS:

CLMS(1)

We claim:

1. A multiple-component bifurcating expandable supportive endoluminal graft comprising:
a plurality of expandable supportive endoluminal components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;
one. . .

CLAIMS:

CLMS(2)

2. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is. . .

CLAIMS:

CLMS(3)

3. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are self-expanding.

CLAIMS:

CLMS(4)

4. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are deployed by a radially expandable device.

CLAIMS:

CLMS(5)

5. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive component includes a generally cylindrical supporting member and a generally. . .

CLAIMS:

CLMS(6)

6. The supportive endoluminal graft in accordance with claim 1, wherein said trunk liner is a stretchable wall of essentially inert biocompatible material, said stretchable. . .

CLAIMS:

CLMS(7)

7. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the generally cylindrical supportive leg component is a stretchable wall of. . .

CLAIMS:

CLMS(8)

8. The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner extend longitudinally beyond said tubular supporting member. . .

CLAIMS:

CLMS(9)

9. The supportive endoluminal graft in accordance with claim 8, wherein said leg portions are separated from each other.

CLAIMS:

CLMS(10)

10. The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner are longitudinally generally coextensive with said tubular. . .

CLAIMS:

CLMS(11)

11. The supportive endoluminal graft in accordance with claim 10, wherein an outside section of each of said leg portions of the trunk liner is. . .

CLAIMS:

CLMS(12)

12. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component, when deployed, is telescopically slidably positioned within one. . .

CLAIMS:

CLMS(13)

13. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the leg component and said trunk liner are each a stretchable. . .

CLAIMS:

CLMS(14)

14. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of each stretchable wall is an elastomeric polymer.

CLAIMS:

CLMS(15)

15. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of said stretchable wall is a polycarbonate urethane.

CLAIMS:

CLMS(16)

16. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material is coated with a thin layer of silicone rubber.

CLAIMS:

CLMS(17)

17. The supportive endoluminal graft in accordance with claim 5, wherein said trunk liner and said liner of the leg component are each a stretchable. . .

CLAIMS:

CLMS(18)

18. The supportive endoluminal graft in accordance with claim 1, wherein an exposed longitudinal end of said tubular supporting member extends longitudinally beyond and is. . .

CLAIMS:

CLMS(19)

19. The supportive endoluminal graft in accordance with claim 17, wherein said tubular supporting member has a plurality of open areas therealong, and said stretchable. . .

CLAIMS:

CLMS(20)

20. The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting member has a plurality of open areas therealong, and an attachment. . .

CLAIMS:

CLMS(21)

21. The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting component includes a plurality of wire strands with open areas therebetween.

CLAIMS:

CLMS(22)

22. The supportive endoluminal graft in accordance with claim 21, wherein said wire strands of the tubular supporting component are generally sinusoidally configured wire that. . .

CLAIMS:

CLMS(23)

23. The supportive endoluminal graft in accordance with claim 21, wherein said wire strands of the tubular supporting component are shaped as intersecting elongated lengths. . .

CLAIMS:

CLMS(24)

24. The supportive endoluminal graft in accordance with claim 1, wherein the endoluminal graft is subjected to surface treatment for enhanced bicompatibility or for drug therapy.

CLAIMS:

CLMS(25)

25. The supportive endoluminal graft in accordance with claim 1, wherein said trunk component includes a projecting securement member.

CLAIMS:

CLMS(26)

26. A multiple-component bifurcating expandable supportive endoluminal graft comprising:
a plurality of expandable supportive endoluminal graft components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible and radially expansible;
one of said expandable supportive endoluminal graft components being a trunk component having a longitudinal axis, an internal surface disposed toward the longitudinal axis, and an external. . . said trunk component having a network of land areas with open areas defined therebetween,
two other of said expandable supportive endoluminal graft components being a generally cylindrical supportive leg component;
said trunk component having a stretchable wall of essentially inert biocompatible material, said. . .

CLAIMS:

CLMS(27)

27. A method for implanting a multi-component bifurcating expandable supportive endoluminal graft, comprising the steps of:
providing a trunk component having a tubular supporting member and a trunk liner positioned along the. . . and expanding the component so as to be deployed at said location in order to form a bifurcated supportive endoluminal graft at a bifurcation site within the body vessel.

CLAIMS:

CLMS(29)

29. . . . beyond the tubular supporting member of the trunk component, and the steps of inserting the leg component insert a supportive stent respectively within the leg portions of the trunk component.

US PAT NO: 5,628,786 [IMAGE AVAILABLE] L1: 21 of 37
TITLE: Radially expandable vascular graft with resistance to longitudinal compression and method of making same

ABSTRACT:
A microporous polytetrafluoroethylene ("PTFE") endovascular graft which has a reinforcing structure integrally bound to the graft which permits radial expansion of the graft and stabilizes the graft against longitudinal compression upon application of an axial force thereto and against axial foreshortening upon radial expansion of the graft. The graft is particularly useful as a covering for an endovascular stent.

SUMMARY:

BSUM(2)

The . . . axial shrinkage or axial foreshortening upon radial expansion. More particularly, the present invention relates to a microporous polytetrafluoroethylene ("PTFE") endovascular graft which has a reinforcing structure integral with or bound to the graft which permits radial expansion of the graft and stabilizes the graft against axial shrinkage upon radial expansion of the graft. Resistance to axial shrinkage is particularly desirable where a vascular graft is mounted onto a radially expandable endoluminal stent or alone onto an expansion balloon for intraluminal delivery and radial expansion.

SUMMARY:

BSUM(4)

Radially . . . stents, all issued to Gianturco, et al., all of which are hereby incorporated by reference for the purpose of exemplifying stent types useful with the longitudinally reinforced grafts of the present invention.

SUMMARY:

BSUM(5)

The . . . as biliary ducts and ureters in an unoccluded condition. In those uses where it may be desirable to cover the stent with a biocompatible material, particularly one which will promote tissue ingrowth, such as PTFE, the stent is covered with the biocompatible material. In the endovascular interventional medical field, endovascular stents may be covered by co-axially disposing a tubular PTFE vascular graft over an endovascular stent, the stent-graft assembly is introduced endovascularly and delivered to the desired location, whereupon the stent-graft assembly is radially expanded, such as by balloon dilatation to secure the stent-graft assembly against the vessel walls.

SUMMARY:

BSUM(6)

Balloon expansion of the stent-graft assembly occurs at pressures sufficient to cause both the stent and the graft to radially expand. As used herein, the terms "axial shrinkage" and "axial foreshortening" are used interchangeably to describe a reduction in the longitudinal length of the graft alone or the graft relative to the longitudinal length of the stent which occurs upon radial expansion of the graft or the graft-stent combination. Axial shrinkage of the graft relative to the associated stent typically results in exposure of the proximal and/or distal end of the stent. Such exposure may, in turn, provide a fluid passageway for body fluids, such as blood, to flow between the abluminal wall of the graft and the luminal wall of the anatomical passageway, e.g., a blood vessel. Such an escaping flow as in, for example, an arterio-venous fistula repair, is undesirable and may be associated with increased mortality and decreased patency of the graft or stent-graft. It is desirable, therefore, to provide a tubular PTFE structure which is resistant to axial shrinkage during radial expansion of. . .

SUMMARY:

BSUM(8)

The . . . present in expanded PTFE (Fleckenstein, et al., U.S. Pat. No. 4,902,290); v) increase radial and longitudinal elasticity of the PTFE graft (Tu, et al., U.S. Pat. No. 5,061,276); vi) provide a self-sealing component to the PTFE graft to seal suture holes or needle punctures (Mano, U.S. Pat. No. 4,304,010); or vii) provide binding sites for pharmacologically active. . .

SUMMARY:

BSUM(14)

It . . . structure made of a biocompatible melt thermoplastic which is integrally bound to the microporous matrix used to make the vascular graft.

DRAWING DESC:

DRWD(3)

FIG. 1 is a perspective view of a vascular graft having a reinforcing structure to resist axial shrinkage during radial expansion.

DRAWING DESC:

DRWD(5)

FIG. . . . elevational view of a second embodiment of the present invention illustrating application of a solvent-borne reinforcing structure to a vascular graft.

DRAWING DESC:

DRWD(6)

FIG. . . . elevational view of the second embodiment of the present invention illustrating application of a solvent-borne reinforcing structure to a vascular graft.

DRAWING DESC:

DRWD(7)

FIG. . . . of a third embodiment of the present invention illustrating a plurality of reinforcing rib structures associated with a tubular vascular graft.

DRAWING DESC:

DRWD(8)

FIG. . . . exploded diagrammatic view of the present invention illustrating the method for applying an integral reinforcing structure to a tubular vascular graft.

DRAWING DESC:

DRWD(9)

FIG. . . . a partial cross-sectional view illustrating a mandrel and a mold used to apply an integral reinforcing structure to a tubular graft in accordance with the method of the present invention.

DRAWING DESC:

DRWD(10)

FIG. 8 is a cross-sectional view taken along line 8--8 of FIG. 7, illustrating a mandrel, mold and vascular graft assembly in accordance with the method of the present invention.

DRAWING DESC:

DRWD(11)

FIG. 9 is a cross-sectional end-elevational view illustrating a second embodiment of the mandrel, mold and vascular graft assembly in accordance with the present invention.

DETDESC:

DETD(2)

Turning now to FIGS. 1-2, there is illustrated a first preferred embodiment of a vascular graft 10 with structural means 16 for imparting the graft 10 with resistance to longitudinal compression or axial shrinkage operably associated with a tubular graft member 12. Tubular graft member 12 has an outer wall surface 13 and a central lumen 14 defining an inner luminal surface 15. Structural. . . the outer wall surface 13 or the luminal wall surface 15. Where the structural means 16 is bonded to the graft 10, bonding may be accomplished by a variety of bonding methods. For example, a bond may be created by mechanical. . . applying positive or negative pressure which causes physical interaction between the structural means 16 and the microporous matrix of the graft member 12. Mechanical bonding may be accomplished by use of melt thermoplastics as the structural means 16, caused to flow. . . Alternatively, the structural means 16 may be chemically bound, such as by cross-linking agents or biocompatible adhesives, to the tubular graft member 12 during manufacture.

DETDESC:

DETD(3)

The structural means 16 may further consist of a reinforcing region 19 formed within the graft member 12 wall thickness between the luminal surface 15 and the outer wall surface 13 of the tubular graft member 12. The method used to form the reinforcing member 16 or the reinforcing region 19 will be more fully. . .

DETDESC:

DETD(4)

In accordance with the preferred embodiment of the present invention, the tubular graft member 12 is made of microporous expanded polytetrafluoroethylene (e-PTFE). The method of making microporous e-PTFE prostheses by paste extrusion and. . .

DETDESC:

DETD(5)

Tubular . . . endoluminal use. A principal difficult associated with endoluminal grafts lies in the means used to attach or anchor the endoluminal graft to eliminate displacement of the graft due to body movements or fluid flow through the anatomical passageway in which the graft is placed, e.g., a blood vessel. As exemplified by Barone, et al., U.S. Pat. No. 5,360,443, issued Nov. 1, 1994, which is hereby incorporated by reference, endovascular stents have been used as an anchoring mechanism when sutured to a graft, endovascularly delivered and radially expanded to exclude an abdominal aortic aneurysm. In Barone, a stent is provided at proximal and distal ends of a graft and is sutured thereto, such that a longitudinal section of the stent is uncovered to provide direct contact between the stent and the intima. The entire assembly is delivered using a delivery catheter and expandable balloon. Upon positioning of the stent in the desired endovascular position, the expandable balloon is pressure dilatated. The radially expansive force from the expanding balloon impinges upon the endovascular stent and causes the stent to radially expand into contact with a luminal surface of the graft and the intimal surface of the vasculature.

DETDESC:

DETD(6)

When used as a covering for an endovascular stent, an e-PTFE vascular graft is radially expanded contemporaneously with the expansion of the endovascular stent. One particular difficulty associated with balloon expansion of a stent-graft assembly is that the balloon will typically assume an bulbous configuration at each of its proximal and distal ends. Balloon expansion typically forces the graft or the stent-graft assembly into a torroidal shape with the proximal and distal ends flaring away from the central axis of the stent-graft assembly with a relatively narrow center section intermediate the flared distal and proximal ends. This phenomenon occurs because there is. . . inflation at each of the proximal and distal ends of the balloon relative to the balloon area covered by the stent-graft assembly. The expansion balloon thus assumes a "dog-bone" configuration with the proximal and distal ends radially expanding to a greater extent that a central region along the longitudinal axis of the stent-graft or graft. The inflation pressure within the balloon exerts a radially expansive force against the balloon along its entire longitudinal axis. However, because the device to be expanded, i.e., a stent-graft assembly or a graff, restrains against radial expansion, the expansion pressures within the balloon act first on the proximal and. . . thereby causing the proximal and distal ends to inflate first, causing the dog-boning effect. The resulting effect is that the graft or the stent-graft assembly is non-uniformly radially expanded along its longitudinal axis.

DETDESC:

DETD(7)

A principal difficulty with stent-graft assemblies, i.e., those in which an endoluminal stent is covered or lined with a graff, lies in the axial foreshortening of the graft relative to the stent upon radial expansion of the stent-graft assembly. Where either a proximal or distal end of the stent is exposed, there is a great probability that the stent will allow body fluids, such as blood in the vascular system or bile where the stent-graft is employed in a biliary duct, to circumvent the stent-graft assembly causing an undesirable leak. Thus, there is an appreciable danger of increased mortality or morbidity where a graft covering longitudinally foreshortens relative to the stent during radial expansion of the stent-graft assembly.

DETDESC:

DETD(8)

Axial foreshortening of a radially expanded graft complicates endoluminal graft or stent-graft delivery. As the graft is radially expanded and longitudinally foreshortens, there is a bunching phenomenon which occurs. The bunching phenomenon results in a greater density of graft material per area of surface area of the expansion balloon. The result of graft material bunching is to increase expansion pressures required to radially expand the graft or

stent-graft assembly to the same diameter over a non-longitudinally foreshortened graff.

DETDESC:

DETD(9)

To guard against undesirable axial foreshortening of the graft upon radial expansion, the inventive reinforced graft member 12 has at least one reinforcing structural support means 16 operably associated therewith. The reinforcing structural support means 16 may consist of alternative reinforcing structures bonded to, co-extruded with, or integrally incorporated within the graft member 12. In accordance with alternative preferred embodiments of the present invention, the reinforcing structural support means 16 is either molded onto a tubular graft member 12 or coated onto tubular graft member 12 by application of a dispersion solution, either in aqueous or colloidal form.

DETDESC:

DETD(10)

Regardless of the manner in which the reinforcing structural support means 16 is produced in association with the tubular graft member 12, the reinforcing structural support means 16 will impart resistance to longitudinal compression and axial foreshortening of the tubular graft member 12. The property of resistance to longitudinal compression and axial foreshortening exists irrespective of the force or impetus which. . . the longitudinal compression or shrinkage. Thus, the property of resistance to longitudinal compression and axial foreshortening will restrain the tubular graft member 12 during radial expansion of the tubular graft member 12, during application of an externally compressive force, or will operate against recoil properties of the e-PTFE material.

DETDESC:

DETD(11)

As . . . reinforcing structural support means 16 is either applied to the outer 13 or inner 11 wall surface of the tubular graft member 12 or incorporated as an integral reinforcing region 19 of the material matrix forming the tubular graft member 12. In accordance with this first preferred embodiment of the reinforced vascular graft 10, the reinforcing structural support means 16 is formed of a biocompatible longitudinally incompressible plastic material, such as a melt. . . is capable of being cured by cross-linking agents into a substantially monolithic structure bonded or integral with the e-PTFE tubular graft material 12.

DETDESC:

DETD(12)

The reinforcing structural support means 16 may also consist of a metallic wire co-extruded with the e-PTFE tubular graft material 12 and positioned within the wall thickness of the e-PTFE tubular graft material 12. Alternatively, the metallic wire structural member is capable of being co-extruded with plastic beading, such as non-expanded PTFE,. . . beading is then mechanically or chemically bonded to the outer 13 or inner 11 wall surface of the e-PTFE tubular graft material 12.

DETDESC:

DETD(13)

Those . . . will appreciate that a myriad of biocompatible materials exist which may be molded with or coated onto an e-PTFE tubular graft member. However, optimum material will have a flow viscosity sufficient to penetrate into a microporous nodefibril matrix of e-PTFE having. . . PTFE. In addition, the optimum material must be substantially incompressible, yet pliable to allow for flexion of the resultant vascular graft.

DETDESC:

DETD(14)

In . . . of a plurality of low-profile rib members bonded to the inner 11 or outer wall surface 13 of the tubular graft member. Bonding of the rib member is enhanced by driving the material used to form the low profile rib member into the microporous material matrix of the e-PTFE material forming the tubular graft member 12. Integration of at least a portion of the rib member into the e-PTFE microstructure may be accomplished by. . . under the influence of positive pressure,

while simultaneously creating a negative pressure on an opposing wall surface of the tubular graft member, such as within the lumen 14 of the tubular graft member 12. The applied positive and negative pressures cooperate to drive the material used for the reinforcing structural support means 16 into the material matrix of the tubular graft member 12 and create a reinforcing region 19 within the wall of the tubular graft member 12. The method and apparatus for pressure forming the reinforcing region 19 and the structural support means 16 will. . .

DETDESC:

DETD(15)

It . . . the reinforcing structural support means 16 or the reinforcing region 19 extend along an entire longitudinal length of the tubular graft member 12. In this manner, at least one longitudinal aspect of the tubular graft member 12 is supported by the reinforcing structural support means 16 against longitudinal compression or axial shrinkage.

DETDESC:

DETD(17)

A length of e-PTFE vascular graft was mounted on a cylindrical mandrel. A corresponding length of non-expanded PTFE beading was longitudinally applied to the outer wall of the e-PTFE vascular graft. The beading and graft were tied with wire at each end to maintain the positioning of the beading on the graft. A heat gun mounted with a thermal tip, was applied only to the beading to sinter the beading. After untying the wire restraints, the graft is visually inspected. Upon visual inspection, the beading appeared to adhere to the graft. Upon manual inspection, however, the beading could be peeled from the outer wall surface of the graft.

DETDESC:

DETD(18)

In the second run of the test, a length of e-PTFE vascular graft was mounted onto a cylindrical mandrel. A corresponding length of non-expanded PTFE beading was longitudinally applied to the outer wall surface of the e-PTFE vascular graft and restrained onto the e-PTFE graft with wire ties at each end. The assembly was loaded into a sintering oven preheated to 375.degree. C. for six minutes, after which the assembly was allowed to cool. Upon visual inspection, the beading appeared to be fully adhered to the graft. The graft was mounted onto an angioplasty balloon and expanded. During radial expansion, the beading dislodged from the graft.

DETDESC:

DETD(19)

A . . . inches (13.8 mm). The FEP tubing was longitudinally applied to the outer wall surface of a length of e-PTFE vascular graft mounted onto a cylindrical mandrel. The FEP tubing was restrained by helically winding high temperature PTFE tape about the entire length of the e-PTFE graft and FEP tubing. The wrapped assembly was placed into a sintering oven preheated to 375.degree. C. for six minutes. During heating, the FEP tape unraveled and the FEP melted and beaded on the e-PTFE graft.

DETDESC:

DETD(20)

A fourth run of the test was conducted, substituting TEFLON thread tape for the high temperature PTFE tape and heating conducted at 265.degree. C., the melt point of FEP, for 5 minutes. The FEP tubing did not melt or stick to the e-PTFE graft.

DETDESC:

DETD(21)

Successive . . . 10.degree. C. with each run. It was not until heating was performed at 295.degree. C. that the FEP melted and adhered to the graft. The FEP-adhered graft from this final test was mounted onto a PALMAZ stent and radially expanded using an angioplasty balloon. Upon radial expansion on the PALMAZ stent, the FEP longitudinal segment maintained adhesion to the graft and did not exhibit any measurable foreshortening from the non-radially expanded condition.

DETDESC:

DETD(22)

Turning . . . used to form the reinforcing structural support means 16. In this second preferred embodiment of the present invention, a tubular graft member 20 is co-axially mounted onto a rotatable mandrel 22. The rotatable mandrel is, in turn, operably coupled to a. . . condition as a coating onto at least one continuous longitudinal section of the outer wall surface 13 of the tubular graft member 20. After coating, the reinforcing material is cured by application of thermal energy or light energy to form a structural coating on the outer wall surface 13 of the tubular graft member 20. Prior to curing, the fluid coating may be driven into the microporous e-PTFE matrix of the tubular graft member 20 by drawing a negative pressure from the central lumen 14 of the tubular graft member 20.

DETDESC:

DETD(24)

An e-PTFE vascular graft was made resistant to axial foreshortening by coating the outside surface of the graft with polytetrafluoroethylene octyphenoxy-polyethoxyethanol aqueous dispersion (FLUON AD-1, ICI Advanced Materials). The FLUON AD-1 aqueous dispersion contains negatively charged PTFE particles. . .

DETDESC:

DETD(25)

A 3 mm outer diameter thin-wall IMPRA graft, 25 cm in length was dipped in FLUON AD-1 to wet the outside surface of the graft. The graft was air dried, blow dried and sintered at 375.degree. C. for four minutes.

DETDESC:

DETD(26)

Longitudinal compression was measured by placing two reference markings one inch apart, manually compressing the uncoated and coated graft on a mandrel to the greatest extent possible and then measuring the distance between the reference markings after compression.

DETDESC:

DETD(28)

To facilitate loading of the fluid-state reinforcing agent onto the e-PTFE graft, the tubular e-PTFE graft may, alternatively, be a carbon-containing graft. In this embodiment, the component of the carbon-containing graft is used as an adsorbent for the fluid-state reinforcing agent. After adsorption onto the carbon contained within the e-PTFE microporous. . . carbon, dispersed throughout the matrix, or lining the luminal or abluminal walls thereof. A preferred process for producing a carbon-containing graft is more fully described in co-pending U.S. patent application Ser. No. 08/311,497, filed Sep. 23, 1994, filed by McHaney, et. . . which is hereby expressly incorporated by reference for the purposes of setting forth a process for making a carbon-containing vascular graft and a carbon-containing vascular graft produced by such process.

DETDESC:

DETD(29)

Turning now to FIGS. 5 and 6, there is disclosed a third embodiment of the invention in which there is a graft member 30 having a central lumen 32 and at least one of a plurality of longitudinally extending rib members 36. The graft member 30 is made in accordance with the extrusion process described in co-pending application Ser. No. 08/134,072, filed Oct. 8,. . . commonly assigned to the assignee hereof, and which is incorporated by reference. Under the Kalis co-pending application, a tubular e-PTFE graft is formed with integral rib structures by extrusion of a PTFE billet, expansion and sintering. In accordance with the preferred. . . members 36 are densified by application of thermal energy to only the rib members 36 without exposing the e-PTFE tubular graft wall surface 33 to thermal energy sufficient to densify the wall surface 33. The thermal energy may include selective heating of the rib members 36 or selective cooling of the rib members 36 during longitudinal expansion of the graft to restrain the rib-members from expansion. This third preferred embodiment of the present invention also contemplates that the rib members. . . the plurality of rib members 32 operate as structural support members which resist longitudinal compression or shrinkage of the tubular graft member 30.

DETDESC:

DETD(31)

A 4 mm inner diameter single ribbed graft made in accordance with the process described in co-pending Kalis patent application Ser. No. 08/134,072, was obtained and sectioned into. . . of each of the seven samples using slight pressure until the rib began to melt and malform. After cooling, each graft was longitudinally compressed manually on the mandrel and the extent of compression measured by measuring the distance between the two. . .

DETDESC:

DETD(33)

We turn now to FIGS. 6-9, which illustrate the preferred method for making the reinforced graft 10 of the present invention. With particular reference to FIGS. 6-8, there is illustrated an vacuum molding assembly 50 for making the inventive reinforced graft 10 of the present invention. Vacuum molding assembly 50 consists generally of a molding mandrel 52 and a vacuum mandrel. . . 64. Vacuum mandrel 62 has an outer diameter having a close fit tolerance with an inner diameter of a tubular graft member 60 such that the tubular graft member 60 may be co-axially engaged thereupon and readily removed therefrom. As an alternative to the plurality of vacuum ports. . . may be formed in the vacuum mandrel 62. So long as at least one entire longitudinal section of the tubular graft member 60 is exposed to a negative pressure from the central vacuum lumen 64, any configuration of suitable vacuum openings. . .

DETDESC:

DETD(35)

In operation, a tubular graft member 60 is mounted onto the vacuum mandrel 62, and the graft 60 mounted vacuum mandrel 62, is co-axially disposed within the lumen of the molding mandrel 52. A negative pressure is. . . along the longitudinal axis of the mold recess 56 and is drawn into the microporous e-PTFE matrix of the tubular graft member 60, thereby forming a reinforcing region within the wall thickness of the tubular graft member 60.

DETDESC:

DETD(36)

An . . . introduce the reinforcing material, in a fluid state, into the mold cover cavity 88 such that it contacts a tubular graft member 60 resident in the mold cover cavity 88 and the mold cavity 84. As with the abovedescribed embodiment, the tubular graft member 60 is carried co-axially on a vacuum mandrel 92 having a vacuum opening 96 passing through at least a. . . mandrel 92, or where the vacuum opening 96 is sufficiently large to cause a large surface area of the tubular graft member 60 into the vacuum opening 96, thereby creating an increased risk of tearing or puncturing the tubular graft member 60, it is desirable to co-axially interdispose a permeable tubular backing member 92 between the tubular graft member 60 and the vacuum mandrel 94. Permeable tubular backing member 92 reinforces the tubular graft member 60 and protects it against tearing or puncturing by impingement upon the edges of the vacuum opening 96, but. . . drawing a negative pressure through it to cause the fluid reinforcing material to penetrate the microporous matrix of the tubular graft member 60.

CLAIMS:

CLMS(1)

What is claimed is:

1. A polytetrafluoroethylene graft, comprising:
a tubular graft member formed of expanded polytetrafluoroethylene having a plurality of nodes and fibrils interconnecting the nodes, and forming a microporous material matrix; and
structural support means for imparting resistance to longitudinal compression or axial shrinkage of the tubular graft member 12. reinforcing the microporous material matrix along a longitudinal axis of the tubular graft member, the structural support means being integrated into at least a portion of the microporous material matrix of the tubular graft member and extending axially along a substantial longitudinal section of the tubular graft member.

CLAIMS:

CLMS(2)

2. The graft of claim 1, wherein said structural support means

further comprises a rib member bonded to at least one of an outer wall surface and an inner wall surface of the tubular graft member.

CLAIMS:

CLMS(3)

3. The graft of claim 2, wherein said rib member further comprises a biocompatible plastic selected from the group consisting of polyamides, polyimides,. . .

CLAIMS:

CLMS(4)

4. The graft of claim 1, wherein said structural support means further comprises an aqueous dispersion of a biocompatible polymer in a coating. . . dispersion being applied to at least one of an inner wall surface and an outer wall surface of said tubular graft member.

CLAIMS:

CLMS(5)

5. The graft of claim 1, wherein said structural support means further comprises a metal member co-extruded with said tubular graft member.

CLAIMS:

CLMS(6)

6. The graft of claim 1, wherein said structural support means further comprises a metal member co-extruded with a polytetrafluoroethylene beading member, said polytetrafluoroethylene beading member being sintered onto said tubular graft member.

CLAIMS:

CLMS(7)

7. The graft of claim 1, wherein said structural support means provides resistance to at least one of longitudinal compression and axial shrinkage of the tubular graft member, said compression of said graft being less than or equal to about 27 percent of the uncompressed length of said graft.

CLAIMS:

CLMS(8)

8. The graft of claim 1, wherein said structural support means further comprises a region integral within the wall thickness of said tubular graft member.

CLAIMS:

CLMS(9)

9. An expanded polytetrafluoroethylene endoluminal graff, comprising:
a radially expandable tubular expanded polytetrafluoroethylene graft member characterized by a microporous material microstructure of nodes interconnected by fibrils and having a first unexpanded diameter and a second radially expanded diameter greater than the first unexpanded diameter; and
a structural support member joined to the graft member, oriented substantially parallel to and extending substantially along an entire longitudinal axis of the tubular graft member, thereby providing longitudinal support to the graft member to restrict longitudinal foreshortening of the graft member during radial expansion of the graft member from the first unexpanded diameter to the second radially expanded diameter.

CLAIMS:

CLMS(10)

10. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, further comprising a radially expandable stent member joined in intimate contact with the radially expandable tubular expanded polytetrafluoroethylene graft member.

CLAIMS:

CLMS(11)

11. The expanded polytetrafluoroethylene endoluminal graft according

to claim 10, wherein the radially expandable stent member is joined to a luminal surface of the radially expandable tubular expanded polytetrafluoroethylene graft member.

CLAIMS:

CLMS(12)

12. The expanded polytetrafluoroethylene endoluminal graft according to claim 10, wherein the radially expandable stent member is joined to an abluminal surface of the radially expandable tubular expanded polytetrafluoroethylene graft member.

CLAIMS:

CLMS(13)

13. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member further comprises a rib member bonded to at least one of an outer wall surface and an inner wall surface of the tubular graft member.

CLAIMS:

CLMS(14)

14. The expanded polytetrafluoroethylene endoluminal graft according to claim 13, wherein the rib member further comprises a biocompatible plastic selected from the group consisting of polyamides,. . .

CLAIMS:

CLMS(15)

15. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member further comprises an aqueous dispersion of a biocompatible polymer in a. . . dispersion being applied to at least one of an inner wall surface and an outer wall surface of said tubular graft member.

CLAIMS:

CLMS(16)

16. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member further comprises a metal member co-extruded with said tubular graft member.

CLAIMS:

CLMS(17)

17. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member further comprises a metal member co-extruded with a polytetrafluoroethylene beading member, said polytetrafluoroethylene beading member being sintered onto said tubular graft member.

CLAIMS:

CLMS(18)

18. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member provides resistance to at least one of longitudinal compression and axial shrinkage of the tubular graft member, said compression of said graft being less than or equal to about 27 percent of the non-compressed length of said graff.

CLAIMS:

CLMS(19)

19. The expanded polytetrafluoroethylene endoluminal graft according to claim 9, wherein the structural support member further comprises a region integral within the wall thickness of said tubular graft member.

US PAT NO: 5,562,726 [IMAGE AVAILABLE] L1: 22 of 37
TITLE: Expandable transluminal graft prosthesis for repair of aneurysm and method for implanting

ABSTRACT:
A transluminal grafting system for grafting a prosthesis to the wall of a lumen includes a tubular graft provided with spring assemblies and anchoring barbs. The prosthesis is mounted on an apertured tubular carrier and a central control. . . and engage the central control

means. An introducer sheath covers the system for smooth insertion into a lumen. When the graft has been positioned, the central control means maintains the axial position of the prosthesis. When the introducer sheath is pulled, the prosthesis is exposed and the spring assemblies return to an expanded state and anchor the graft against the internal wall of the lumen.

SUMMARY:

BSUM(2)

The invention relates to transluminal graft prostheses for the repair of aneurysms and a method for implanting them.

SUMMARY:

BSUM(4)

The . . . incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

SUMMARY:

BSUM(5)

Such . . . The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant. . .

SUMMARY:

BSUM(7)

U.S. . . . is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to. . .

SUMMARY:

BSUM(8)

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on. . . to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts. . . repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

SUMMARY:

BSUM(9)

The . . . of Diagnostic Radiology, University of Texas M.D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming. . . compressed radially, and is introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the catheter while holding the introducer wire stationary. This. . . rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the

graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one of these grafts carried barbs. The other model showed. . . . a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter.. . .

SUMMARY:

BSUM(10)

Endovascular . . . lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

SUMMARY:

BSUM(11)

The . . . this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY:

BSUM(13)

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

SUMMARY:

BSUM(16)

The . . . of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . .

SUMMARY:

BSUM(17)

The . . . lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . . device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and. . .

SUMMARY:

BSUM(18)

The . . . assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the

graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end,. . .

SUMMARY:

BSUM(21)

The . . . and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally. . .

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a tubular graft of the instant invention;

DRAWING DESC:

DRWD(7)

FIG. 6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

DRAWING DESC:

DRWD(17)

FIG. 15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

DRAWING DESC:

DRWD(19)

FIG. 18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

DRAWING DESC:

DRWD(21)

FIG. 20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

DRAWING DESC:

DRWD(22)

FIG. 21 depicts a segment of a self-expanding stent;

DRAWING DESC:

DRWD(23)

FIG. 22 depicts a bifurcated graft;

DRAWING DESC:

DRWD(27)

FIG. 28 depicts tubular extensions sutured to a graft of the present invention;

DRAWING DESC:

DRWD(28)

FIG. 29 depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

DRAWING DESC:

DRWD(36)

FIG. 39 depicts a distal stent insertion device of the present invention;

DETDESC:

DETD(2)

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron.TM.), which is known to be. . . material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

DETDESC:

DETD(3)

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide. . . a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

DETDESC:

DETD(4)

The . . . apertured 60. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurved arches 42 is that they collapse more readily and are more durable.. . . barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such. . . have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft 1 would be in less intimate contact with the wall of the lumen.

DETDESC:

DETD(5)

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft 1 or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that. . . and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact. . . both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the graft 1 to provide a more secure anchor in the direction of blood flow. The barbs 10 are positioned so that. . .

DETDESC:

DETD(6)

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to. . . overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the

joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has. . .

DETDESC:

DETD(7)

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGS. 9-A and 9-B, the joint is more flexible when the spring assemblies 64. . . d.sub.2). Thus, because .alpha. is larger than .beta., the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

DETDESC:

DETD(10)

FIG. . . . tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath. . .

DETDESC:

DETD(11)

"Muzzle loading" involves inserting the graft 1, already mounted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4. . .

DETDESC:

DETD(12)

"Muzzle . . . loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to. . . totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

DETDESC:

DETD(13)

The . . . over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially. . .

DETDESC:

DETD(14)

FIG. . . . iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted in the aorta 2 at the site of the aortic aneurysm 20.

DETDESC:

DETD(15)

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled,. . .

DETDESC:

DETD(18)

In . . . into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

DETDESC:

DETD(21)

All . . . devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1 during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including. . . of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially. . .

DETDESC:

DETD(22)

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

DETDESC:

DETD(23)

The . . . of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly. . . tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring. . . means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may. . . 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a. . . of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer. . .

DETDESC:

DETD(24)

FIG. . . . catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

DETDESC:

DETD(25)

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the. . .

DETDESC:

DETD(26)

The . . . open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy. . . sheath 4 is pulled back exposing

the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass. . . . tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn. . . . and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present). . . . past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26,. . .

DETDESC:

DETD(27)

Aortic . . . iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such. . . contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends. . .

DETDESC:

DETD(28)

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

DETDESC:

DETD(30)

When . . . percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

DETDESC:

DETD(31)

Hereinafter described is a bifurcated endovascular graft 150 and the method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

DETDESC:

DETD(32)

The prosthesis comprises a graft and one or more stents. Stents

occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

DETDESC:

DETD(33)

All . . . the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

DETDESC:

DETD(34)

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251. . .

DETDESC:

DETD(35)

Grafts . . . may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

DETDESC:

DETD(36)

In . . . common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

DETDESC:

DETD(37)

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with. . . fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

DETDESC:

DETD(46)

The . . . control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGS. 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

DETDESC:

DETD(47)

As . . . FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches. . . suture 252 and 253 that pass along the wall of respective tubular extensions 246 and 247 to the junction with graft 206.

DETDESC:

DETD(48)

Alternatively, . . . caudal limb control suture 154 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256. . . and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when. . .

DETDESC:

DETD(49)

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter. . .

DETDESC:

DETD(50)

As . . . traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216. . .

DETDESC:

DETD(51)

As . . . used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 254 is also required on ipsilateral distal limb 213.

DETDESC:

DETD(54)

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

DETDESC:

DETD(55)

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external. . . sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath.. . . the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of 35 caudal stent 275.

DETDESC:

DETD(56)

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. Straightening device 130 is advanced over the distal limb control system onto the end of the distal. . . of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

DETDESC:

DETD(57)

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132. . . maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the. . .

reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

DETDESC:

DETD(62)

An . . . that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in. . .

DETDESC:

DETD(63)

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method, a Dormier basket is passed up the ipsilateral. . .

DETDESC:

DETD(65)

The . . . of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath 217 exposes the caudal limb control mechanisms and their. . . carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral. . .

DETDESC:

DETD(67)

Stents . . . required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used,. . . is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

DETDESC:

DETD(68)

The . . . the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory,. . .

CLAIMS:

CLMS(1)

What is claimed is:

1. A self-expanding prosthesis for repairing an aneurysm, comprising:
a bifurcated endovascular graft having a main body and first and second limbs extending therefrom, said main body including a main bore extending longitudinally. . . marker extending longitudinally along said first limb and spaced at least a predetermined distance away from said first marker;
a self-expanding stent positioned in said main bore about said cranial orifice;
a tubular introducer sheath having a single wall and a sheath bore. . . and shaft regions and being smaller than said constant diameter of said sheath bore for positioning coaxially said self-expanding cranial stent, said main body and at least one of said first and said second limbs of said graft therearound and in said sheath bore.

CLAIMS:

CLMS(2)

2. The prosthesis of claim 1 wherein said self-expanding cranial stent includes at least one barb.

CLAIMS:

CLMS(3)

3. The prosthesis of claim 1 further comprising a first caudal stent positionable in said first bore.

CLAIMS:

CLMS(4)

4. The prosthesis of claim 3 wherein said first caudal stent includes at least one barb.

CLAIMS:

CLMS(5)

5. The prosthesis of claim 3 further comprising a second caudal stent positionable in said second bore.

CLAIMS:

CLMS(6)

6. The prosthesis of claim 5 wherein said second caudal stent includes at least one barb.

CLAIMS:

CLMS(9)

9. . . .
including a second bore extending longitudinally therein, communicating with said main bore, and having a second caudal orifice;
providing a self-expanding stent positioned in said main bore about said cranial orifice;
providing a first radio-opaque, imageable marker extending longitudinally along said first limb;
providing. . . and shaft regions and being smaller than said constant diameter of said sheath bore for positioning coaxially said self-expanding cranial stent said main body and at least one of said first and said second limbs of said prosthesis therearound and in. . .

US PAT NO: 5,549,663 [IMAGE AVAILABLE] L1: 23 of 37
TITLE: Endoprosthesis having graft member and exposed welded end junctions, method and procedure

ABSTRACT:
An endoprosthesis is provided which includes a stent component and a graft component capturing a portion of the stent component. The stent component is made of generally malleable material arranged to provide the stent component with a collapsed transluminal positioning configuration and an expanded, deployed configuration. The stent component has adjacent end windings that are welded together. In a preferred arrangement, a plurality of these welds define a spine-like welded arrangement, and a number of these arrangements are positioned generally circumferentially around the ends of the stent component. The graft component extends generally between the welded end portions of the stent component, with limited overlap being possible. Also provided is a method for forming this endoprosthesis and a procedure by which. . .

SUMMARY:

BSUM(3)

The . . . generally relates to endoprostheses and to their preparation and use. More particularly, the invention relates to an endoprosthesis having a stent component with adjacent windings composed of undulating bendable segments that are oriented in a generally helical pattern along the length. . . . to the endoprosthesis. A number of adjacent windings at each axial end portion of the endoprosthesis are welded together. A graft component closely overlies the outer and inner cylindrical surfaces of the stent component such that the axial end portions of the stent component are uncovered. The welded portions add rigidity to the endoprosthesis ends and assist in maintaining the position and patency. . .

SUMMARY:

BSUM(4)

Various so-called stent devices have been developed or proposed for use in association with angioplasty treatments and other medical treatments or procedures wherein devices having expandable components, such as balloon catheters, are used to treat a condition with a body vessel. The stent is in the nature of a device, usually tubular or cylindrical in shape, which is deployed by a balloon or. . . . 5,133,732 proposes longitudinal over-stretch limiting means such as by attaching a longitudinal wire generally parallel to the axis of the stent.

SUMMARY:

BSUM(5)

Graft devices are also known, grafts being in the nature of woven, wound or molded cylinders or the like that are. . . . surgical procedures. It has been proposed that grafts can be deployed through percutaneous placement by combining the features of a stent-like device with those of a graft. Deployment in this regard would be by way of a percutaneous transluminal angioplasy balloon or other device that can be. . . . place for deployment purposes. One potential difficulty with these types of combination devices is a means for insuring that the graft will remain in place after deployment for extended lengths of time. It is particularly important that any anchoring arrangements also. . . .

SUMMARY:

BSUM(6)

Endoprostheses . . . ability to be percutaneously and transluminally deployed with excellent patency while also affording good rigidity to certain portions of the stent component in order to enhance the anchoring attributes of the stent-like components of the device. Endoprostheses of the present invention also exhibit the ability to follow the contour of the vessel. . . .

SUMMARY:

BSUM(7)

In . . . . in an undulating fashion, which undulating strand is wound in a generally helical configuration to form the body of the stent portion of the endoprosthesis, same being composed of a plurality of full circle windings continuous with each other along the. . . . adjacent end windings, preferably along a plurality of spinal weld patterns that follow the contour of the adjacent windings. A graft component covers the central length of the stent component while a substantial portion of the welded end lengths protrude longitudinally beyond the graft component. Graft materials sandwich the central portion of the stent component between inner and outer walls of graft material. In an especially preferred embodiment for manufacturing the endoprosthesis, the inner graft member is spun onto a mandrel, the formed and welded stent component is placed thereover, and an outer graft member is spun over the central length of the stent component in a manner to effect adherence of the inner and outer graft members together to capture the stent member therebetween.

SUMMARY:

BSUM(8)

It is accordingly a general object of the present invention to provide an improved endoprosthesis having a graft component at its central portion and a welded stent component at its ends, as well as the making and use of same.

SUMMARY:

BSUM(10)

Another object of this invention is an improved endoprosthesis and procedure for deploying same which includes anchoring uncovered stent ends within a body vessel wall.

SUMMARY:

BSUM(12)

Another object of this invention is to provide an improved endoprosthesis and deployment procedure whereby stent spines add rigidity to endoprosthesis ends and maintain the position and patency of the graft of the endoprosthesis.

DETDESC:

DETD(4)

With more particular reference to the endoprosthesis 11, the illustrated embodiment includes a stent component 21 constructed of a strand of metal or polymer which exhibits malleability adequate to be formed into shapes such. . .

DETDESC:

DETD(5)

A . . . along the circumference of the endoprosthesis. Each such grouping or spine generally follows pitch angle "A", which substantially follows the graft helix that is defined by adjacent connecting portion pairs 17, 17 of adjacent windings.

DETDESC:

DETD(7)

As . . . is presented between the welded groupings as illustrated in the preferred embodiment. Generally speaking, the larger the circumference of the stent member, the greater the number of weld spines can be accommodated. Different spacings are also possible. It will be appreciated. . .

DETDESC:

DETD(10)

More . . . it is at present generally accepted that the supporting surface area (typically the "metal" outside or working surface of the stent) is to constitute between about 12% and about 15% of the cylindrical surface defined by the stent. Otherwise, inadequate support will be provided. This means that, under present beliefs, it is desirable to have between about 85% and about 88% open space presented by the external cylindrical definition of a stent component. The configuration of the welded end portions of the stent component of the invention is tailored to fall within these guidelines. More importantly, the amount of supportive surface area or "metal" presented to the vessel by the stent is a consistent percentage throughout the length and circumference of the welded ends. Accordingly, if 12 to 15% supporting surface. . .

DETDESC:

DETD(11)

With more particular reference to the welds 18 of the stent component 21 of the endoprosthesis, they are preferably formed by a fusion welding procedure, such as electron beam welding, laser. . .

DETDESC:

DETD(12)

Strand material out of which the stent component 21 of the endoprosthesis according to the invention is made must be capable of forming a joint under welding. . . high molecular weight polyethylenes, carbon fibers, Kevlar polymer, and the like. It is also possible to coat these materials after stent formation has been completed with porous or textured surfaces for cellular ingrowth and the like or with non-thrombogenic agents such. . . can also be carried out so that drugs or medicines can be eluted therefrom. It is also possible that certain stent components may be made of biodegradable materials. The strand material must, of course, be biocompatible. Tantalum is the especially preferred. . .

DETDESC:

DETD(13)

In addition to the stent component 21, endoprostheses in accordance with the present invention include a graft component, generally designated as 22 in FIG. 4. Graft component 22 includes both an interior graft member 23 and an exterior graft member 24. The interior and exterior graft members typically have the same longitudinal length, although the exterior graft member 24 could be longer than the interior graft member 23 if desired. In essence, the interior graft member serves as an attachment base for the exterior graft member to incorporate the stent member therebetween.

DETDESC:

DETD(14)

While the graft component could be made of various different materials and in various different configurations, such as those which are woven, non-woven, spun, molded, extruded and the like, the preferred graft component has a non-woven, spun configuration. It is especially preferred that this material be made by a winding procedure such. . . as feed to the multiple-nozzle ejector 28. The combination of the rotating mandrel and reciprocating shuttle assembly forms the non-woven graft material illustrated wherein individual strands cross underlying strands. It will be appreciated that the spinnable polymer freshly extruded through the nozzles will lie down over and be generally adhered to underlying strands which had been previously laid down, particularly those which cross each other.

DETDESC:

DETD(15)

It . . . down these strands in a single helical pattern. In that event, an ejector having enough nozzles to lay down a ribbon formed of these strands during one pass can be used to lay down a helical internal ribbon in which event the shuttle would not be used. Whether a single helical pattern is used or crossing helical patterns. . . angle of the single helical pattern or of one of the helical patterns will approximate the pitch angle of the stent component. When the endoprosthesis is expanded, these pitch angles will accordingly enlarge, generally to about the same extent.

DETDESC:

DETD(16)

In the illustrated embodiment, the interior graft member 23 is first formed on the mandrel in accordance with the procedure illustrated in FIG. 2. Thereafter, the stent component 21 is fitted thereover. Typically, this can include trimming the interior graft member 23 to the desired length, after which the stent component is slid thereover while the graft member 23 is still on the mandrel. This approach is convenient for formation of the exterior graft member 24 directly onto the same mandrel by following substantially the same procedure as illustrated in FIG. 2. When thus laid down, it is preferred that the inner graft member strands and especially the outer graft member strands are not fully cured. As a result, bonding takes place between the strands of the inner and outer members throughout the length of the center of the stent component. The central length of the stent component is enveloped in or captured by the graft component 22 as generally shown in FIGS. 4 and 5. After assembly is complete, the edges of the graft component are preferably trimmed.

DETDESC:

DETD(17)

It is desired that the graft component overlap with the end lengths 19, 20 of the stent component. Preferably this overlap is such that a maximum of approximately twenty-five percent of the welds 18 of these end lengths are covered by the inner and outer graft material. This insures that the combination will be held together without buckling or pleating. Enough of the welded end lengths are to be uncovered, at least by the exterior graft member 24, so that a substantial portion of the end lengths expand without any significant constraint by the graft component to ensure full and uniform deployment of the welded end lengths as discussed herein. Superior stenting and anchoring result. In addition, a sufficient extent of the end lengths of the stent component should be uncovered by the graft materials to facilitate having the graft ends maintain patency and proper endoprosthesis positioning. Uses in abdominal or aortic applications are especially suitable for these types of. . .

DETDESC:

DETD(18)

Materials suitable for making the graft component include polytetraethylene (PTE), EPTE, polytetrafluoroethylene, nylons, polyamides, as well as other polymers such as Gortex and Dacron fibers, bioabsorbables. . . of the same or different materials. Treatment materials such as drugs and anticoagulants may be incorporated, especially on the exterior graft member. When the graft component is to be a spun fiber component, it is important that the polymer be fiber forming in air so. . .

DETDESC:

DETD(19)

The formed graft component preferably is compliant enough to be able to readily follow the stent component, especially during its

expansion, while also being of low elasticity so as to not significantly interfere with the ability of the stent component to maintain the endoprosthesis in its deployed condition. For example, a recoil of not greater than about 7 percent, preferably between about 5 and about 7 percent is suitable for a preferred graft material. Should the material exhibit inadequate compliance or excessive recoil or elasticity, the components of the endoprosthesis will tend to separate from one another, and/or develop ripples. Preferably, the graft member moves through its plastic state, or is plastically deformed, during endoprosthesis deployment so it will be stretched and expanded by the stent component and remain so after implantation is complete. Also graft structures, such as meshes, can exhibit elasticity due to the pattern of the fibrils. Whatever the graft member structure or material, the recoil force exerted on the stent component cannot be greater than the magnitude of radial force which will deform or collapse the stent component.

DETDESC:

DETD(20)

As discussed herein, the endoprosthesis of the invention can be deployed by means of a balloon catheter. Alternatively, the stent component and hence the endoprosthesis can be self-expanding. Such a stent component is made of nickel-titanium alloys or Nitinol alloys, or other materials which rapidly change in configuration or size when a temperature threshold is achieved. For example, a self-expanding endoprosthesis having a stent made of Nitinol alloy can be deployed into a blood vessel at an implantation diameter. When the treatment site is. . .

CLAIMS:

CLMS(1)

I claim:

1. An implantable transluminal endoprosthesis, comprising:
a malleable strand having a generally helical configuration to form a stent component having a plurality of full circle windings along a generally helically axis, the stent component having an interior surface and an exterior surface, the stent component extending the length of the endoprosthesis;
said malleable strand including a repeating pattern of undulations that follow said generally helical. . . generally opened orientation with respect to each other and with respect to said bendable connecting portions at said expanded circumference;
said stent component having end lengths, each said end length having a plurality of welds joining the end windings to their respective adjacent winding in order to define welded end lengths of the stent component;
a graft component having an inner member and an outer member closely overlying said interior surface and exterior surface respectively of said stent component such that a portion of each of said welded end lengths is covered by said graft component inner and outer members and such that a substantial axially extending portion of each of said welded end lengths protrudes longitudinally beyond said graft component and said graft member covers at least the central portion of the stent component, said central portion being between said welded end lengths of the stent component; and
said graft component exhibits compliance adequate to radially expand with the stent member and a low recoil percentage once thus expanded.

CLAIMS:

CLMS(2)

2. The endoprosthesis in accordance with claim 1, wherein said outer member of the graft component has a length at least as great as that of the inner member of the graft component, and said inner and outer graft members are adhered together with a portion of said stent component incorporated therebetween.

CLAIMS:

CLMS(3)

3. The endoprosthesis in accordance with claim 1, wherein said graft component covers not greater than approximately one quarter of said welded end length.

CLAIMS:

CLMS(4)

4. The endoprosthesis in accordance with claim 2, wherein said graft

component covers not greater than approximately one quarter of said welded end length.

CLAIMS:

CLMS(5)

5. The endoprosthesis in accordance with claim 1, wherein said recoil of the graft component is no greater than about seven percent.

CLAIMS:

CLMS(6)

6. . . . the end lengths, each of said weld spines having a pitch angle substantially along said generally helical axis of the stent component.

CLAIMS:

CLMS(7)

7. An implantable transluminal endoprosthesis, comprising:
a malleable strand having a generally helical configuration to form a stent component having a plurality of full circle windings along a generally helically axis, the stent component having an interior surface and an exterior surface, the stent component extending the length of the endoprosthesis;
said malleable strand including a repeating pattern of undulations that follow said generally helical. . . generally opened orientation with respect to each other and with respect to said bendable connecting portions at said expanded circumference;
said stent component having end lengths, each said end length having a plurality of welds joining the end windings to their respective adjacent winding in order to define welded end lengths of the stent component, wherein said welds are fusion welds;
a graft component having an inner member and an outer member closely overlying said interior surface and exterior surface respectively of said stent component such that a portion of each of said welded end lengths is covered by said graft component inner and outer members and such that a substantial axially extending portion of each of said welded end lengths protrudes longitudinally beyond said graft component and said graft member covers at least the central portion of the stent component, said central portion being between said welded end lengths of the stent component; and
said graft component exhibits compliance adequate to radially expand with the stent member and a low recoil percentage once thus expanded.

CLAIMS:

CLMS(9)

9. . . . in accordance with claim 1, wherein said plurality of welds impart increased hoop strength to said end lengths of the stent component which is greater than the hoop strength of the remainder of the endoprosthesis.

CLAIMS:

CLMS(10)

10. An implantable transluminal endoprosthesis, comprising:
a malleable strand having a generally helical configuration to form a stent component having a plurality of full circle windings along a generally helically axis having a pitch angle, the stent component having an interior surface and an exterior surface, the stent component extending the length of the endoprosthesis;
said malleable strand including a repeating pattern of undulations that follow said generally helical. . . generally opened orientation with respect to each other and with respect to said bendable connecting portions at said expanded circumference;
said stent component having end lengths, each said end length having plurality of welds joining the end windings to their respective adjacent winding order to define welded end lengths of the stent component;
a graft component having an inner member and an outer member closely overlying said interior surface and exterior surface respectively of said stent component such that a portion of each of said welded end lengths is covered by said graft component inner and outer members and such that a substantial axially extending portion of each of said welded end lengths protrudes longitudinally beyond said graft component and said graft member covers at least the central portion of the stent component, said central portion being between said welded end lengths of the stent component;
said graft component includes fibers wound at a given pitch angle which approximates said pitch angle of the stent component; and

said graft component exhibits compliance adequate to radially expand with the stent member and a low recoil percentage once thus expanded.

CLAIMS:

CLMS(11)

11. An implantable transluminal endoprosthesis, comprising:
a malleable strand having a generally helical configuration to form a stent component having a plurality of full circle windings along a generally helically axis, the stent component having an interior surface and an exterior surface, the stent component extending the length of the endoprosthesis;
said malleable strand including a repeating pattern of undulations that follow said generally helical. . . generally opened orientation with respect to each other and with respect to said bendable connecting portions at said expanded circumference;
said stent component having end lengths, each said end length having a plurality of welds joining the end windings to their respective adjacent winding order to define welded end lengths of the stent component;
a graft component having an inner member and an outer member closely overlying said interior surface and exterior surface respectively of said stent component such that a portion of each of said welded end lengths is covered by said graft component inner and outer members and such that a substantial axially extending portion of each of said welded end lengths protrudes longitudinally beyond said graft component and said graft member covers at least the central portion of the stent component, said central portion being between said welded end lengths of the stent component;
said outer member of the graft component is treated with a drug or an anticoagulant; and
said graft component exhibits compliance adequate to radially expand with the stent member and a low recoil percentage once thus expanded.

CLAIMS:

CLMS(12)

12. The endoprosthesis in accordance with claim 1, further including barbs secured to the stent component at said welded end lengths.

CLAIMS:

CLMS(13)

13. The endoprosthesis in accordance with claim 1, wherein said stent component malleable material is made of an energy-sensitive material, and said stent component expands diametrically when subjected to energy to which the malleable material is sensitive.

US PAT NO: 5,486,593 [IMAGE AVAILABLE] L1: 24 of 37

SUMMARY:

BSUM(19)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

SUMMARY:

BSUM(34)

The . . . means, Which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

SUMMARY:

BSUM(35)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast

bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(38)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication or devices such as vascular graft; striated fibers may be used in the fabrication or devices as ligament or tendon prosthesis to encourage certain alignment of. . .

SUMMARY:

BSUM(45)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

SUMMARY:

BSUM(46)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pre-treatment. . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

SUMMARY:

BSUM(90)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

SUMMARY:

BSUM(91)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(137)

Completely Bioresorbable Graft-Fabrication

DETDESC:

DETD(146)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(147)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(148)

A . . . coating polymer, e.g., the random copolymer of 91% TMC-9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(154)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(159)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(171)

Fabrication of Rod and Ribbon as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(172)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(173)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(174)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(175)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(211)

Similarly, . . . did coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(216)

Cloth . . . various bioresorbable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(227)

Fabrication of Rod and **Ribbon** as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(228)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or **ribbon** produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(234)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to **adhere** unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,412,068 [IMAGE AVAILABLE] L1: 25 of 37

SUMMARY:

BSUM(20)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular **graft** body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

DETDESC:

DETD(4)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular **graft**. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular **graft**, or a **stent** for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

DETDESC:

DETD(5)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular **graft** composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the **graft**. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

DETDESC:

DETD(8)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular **graft**; striated fibers may be used in the fabrication of devices as ligament or tendon prosthesis to encourage certain alignment of. . .

DETDESC:

DETD(15)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular **graft** applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30

mm.

DETDESC:

DETD(16)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

DETDESC:

DETD(63)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

DETDESC:

DETD(64)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(209)

Completely Bioresorable Graft-Fabrication

DETDESC:

DETD(218)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(219)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(220)

A . . . coating polymer, e.g., the random copolymer of 91% TMC-9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(227)

For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(232)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer by 50% weight gain were implanted in two adult sheep as bilateral carotid

replacement. One. . .

DETDESC:

DETD(244)

Fabrication of Rod and **Ribbon** as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(245)

1. . . . six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 1 mm vascular **graft** (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the **graft** so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The **graft** did not kink or collapse upon bending.

DETDESC:

DETD(246)

2. . . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular **graft**. The **graft** was also coated as before. The benefit of not kinking and collapsing was also achieve.

DETDESC:

DETD(247)

3. . . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final **ribbon** size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular **graft** in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(248)

4. Similarly, the rod or **ribbon** can be applied to a completely bioresorbable **graft** since the bioresorbable yarn used to fabricate the totally bioresorbable **graft** was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(284)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(289)

Cloth . . . various bioresorbable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(300)

Fabrication of Rod and **Ribbon** as Internal Support in Conjuction with Balloon Angioplasty

DETDESC:

DETD(301)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or **ribbon** produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(307)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care is spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,387,235 [IMAGE AVAILABLE] L1: 26 of 37
TITLE: Expandable transluminal graft prosthesis for repair of aneurysm

ABSTRACT:
A . . . the bifurcated lumen of the aorta and the common iliac arteries extending therefrom. The prosthesis assembly includes a bifurcated endovascular graft having a main body and ipsilateral and contralateral limbs extending therefrom. The assembly also includes main, ipsilateral, and contralateral spring assemblies each having a compressed state. When released from its compressed state, each spring expands a portion of the graft to substantially conform that portion of the graft to the wall of the bifurcated lumen. The transluminal arrangement comprises an elongated member extending through the main and ipsilateral bores of the graft and includes attachment sutures and an inner catheter extending therethrough for temporarily attaching the main and ipsilateral spring assemblies to the elongated member. An outer sheath contains the attached prosthesis assembly, whereas stent boots consisting of short length sheaths contain the ipsilateral and contralateral spring assemblies. A control limb delivery catheter and attachment sutures maintain the contralateral graft limb and spring assembly in the stent boot for placement in the contralateral iliac artery.

SUMMARY:

BSUM(2)

The invention relates to transluminal graft prostheses for the repair of aneurysms and a method for implanting them.

SUMMARY:

BSUM(4)

The . . . incision, dissection of the arteries, and the interruption of blood flow to the lower body and legs while an artificial graft is implanted to bypass the aneurysm.

SUMMARY:

BSUM(5)

Such . . . The present invention serves these needs, and is particularly well adapted to reconstruction of an abdominal aortic aneurysm. The prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture, without the attendant. . .

SUMMARY:

BSUM(7)

U.S. . . . is mechanically complex and may not apply sufficient force to drive the pins into an atherosclerotic aorta or seal the graft to the arterial lumen. Furthermore, there is nothing to shield the vessel wall from the sharp pins while the device is moving from the insertion point to the point of repair. The pins are interspaced in folds of the graft material and could protrude from these folds while the device is moved into position. This could result in damage to. . .

SUMMARY:

BSUM(8)

U.S. Pat. No. 4,787,899, issued to Lazarus, describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal (upstream) end of the graft onto the wall of the lumen, and then the guide is pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen, where staples at the proximal (downstream) end anchor into the wall of the lumen. Because the graft is folded or crimped axially, there is no sure method of determining where the expanded graft will position itself on the wall of the lumen, other than by measuring from the point of initial contact on. . . to do utilizing the remote insertion procedure. Also, the balloon providing the anchor for the distal (upstream) end of the graft while the guide is moved upstream may not

provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft. The axial crimping used in these grafts may not impart radial elasticity and standard graft materials may not have sufficient elasticity as an intrinsic property. The small amount of apparent elasticity present in knitted grafts. . . repaired, rather than via a distant (much smaller) vessel. Also, the large guide may be difficult to withdraw through the graft after placement since it presents an open edge which might catch on any irregularities of the lumen.

SUMMARY:

BSUM(9)

The . . . Diagnostic Radiology, University of Texas M. D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. Two stainless steel struts run down the length of the chain, forming. . . compressed radially, and is introduced into a lumen via a catheter and a blunt-tipped introducer wire used to push the graft up the catheter and into position. Placement is secured by withdrawing the catheter while holding the introducer wire stationary. This. . . rigidity would make it very difficult to negotiate femoral and iliac arteries which are frequently tortuous. Precise positioning of the graft could be impaired because the pusher wire is not attached to the graft. This poses the potential for mispositioning of the graft during the withdrawal of the sheath. Hemorrhage could also be a major problem with this method of introduction. The introducer sheath is carried into position on the outside of a dilator, which must be removed before the graft can be inserted, leaving the sheath as a conduit from the artery to the outside of the body. The need to introduce the graft complicates the use of hemostatic seals on the sheath. Only one of these grafts carried barbs. The other model showed. . . a possibility that the sheathed wall of the barbed device could be breached by the barbs during transfer of the graft to the point of repair because the graft is pushed though the entire length of the catheter with the springs expanded against the inner wall of the catheter.. . .

SUMMARY:

BSUM(10)

Endovascular . . . lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

SUMMARY:

BSUM(11)

The . . . this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

SUMMARY:

BSUM(13)

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

SUMMARY:

BSUM(16)

The . . . of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . .

SUMMARY:

BSUM(17)

The . . . lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of. . . device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and. . .

SUMMARY:

BSUM(18)

The . . . assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end,. . .

SUMMARY:

BSUM(21)

The . . . and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally. . .

SUMMARY:

BSUM(25)

The . . . the common iliac arteries. A prosthesis assembly for positioning in the aneurysm of the bifurcated lumen includes a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The assembly also includes main and branch limb spring. . . each having a compressed state. The main bore spring assembly radially expands to substantially conform the main body of the graft to the interior wall of the aortal lumen. The ipsilateral and contralateral limb spring assemblies radially expand to conform the limbs of the graft to the interior walls of the branch lumens of the ipsilateral and contralateral iliac arteries. The transluminal arrangement comprises containers. . . the spring assemblies in a compressed state and a retainer assembly positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly at the aneurysm in the bifurcated lumen while the main outer sleeve is withdrawn from. . .

SUMMARY:

BSUM(29)

The . . . when positioned at the aneurysm in the bifurcated lumen allowing the main spring assembly to radially expand and conform the graft to the aorta. The branch limb containers of the transluminal arrangement are also withdrawn from the branch spring assemblies which then radially expand the ipsilateral and contralateral limbs of the graft to the common iliac arteries so as to advantageously prevent retrograde flow of blood back to the aneurysm. Similarly, the main spring assembly conforms the cranial orifice of the main body of the graft to the wall of the aorta preventing antegrade flow of blood into the aneurysm.

DRAWING DESC:

DRWD(2)

FIG. 1 is a side view of a tubular graft of the instant invention;

DRAWING DESC:

DRWD(7)

FIG. 6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

DRAWING DESC:

DRWD(17)

FIG. 15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

DRAWING DESC:

DRWD(19)

FIG. 18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

DRAWING DESC:

DRWD(21)

FIG. 20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft.

DRAWING DESC:

DRWD(22)

FIG. 21 depicts a segment of a self-expanding stent;

DRAWING DESC:

DRWD(23)

FIG. 22 depicts a bifurcated graft;

DRAWING DESC:

DRWD(27)

FIG. 28 depicts tubular extensions sutured to a graft of the present invention;

DRAWING DESC:

DRWD(28)

FIG. 29 depicts an alternative mechanism for attaching the tubular extensions to a graft of the present invention;

DRAWING DESC:

DRWD(36)

FIG. 39 depicts a distal stent insertion device of the present invention;

DRAWING DESC:

DRWD(41)

FIG. 44 depicts a partially sectioned side view of ipsilateral limb spring assembly of the prosthesis assembly and stent boot of the transluminal arrangement of FIG. 43;

DRAWING DESC:

DRWD(43)

FIG. 46 depicts a partially sectioned side view of contralateral stent boot temporarily attached to control limb delivery catheter of FIG. 45;

DETDESC:

DETD(2)

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct

the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron.TM.), which is known to be. . . material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

DETDESC:

DETD(3)

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself. A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide. . . a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

DETDESC:

DETD(4)

The . . . apertured 60. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurved arches 42 is that they collapse more readily and are more durable.. . . barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such. . . have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft I would be in less intimate contact with the wall of the lumen.

DETDESC:

DETD(5)

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft 1 or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that. . . and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact. . . both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the graft 1 to provide a more secure anchor in the direction of blood flow. The barbs 10 are positioned so that. . .

DETDESC:

DETD(6)

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to. . . overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has. . .

DETDESC:

DETD(7)

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft

has been implanted. As shown in FIGS. 9-A and 9-B, the joint is more flexible when the spring assemblies 64. . . d.sub.2). Thus, because .alpha. is larger than .beta., the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

DETDESC:

DETD(10)

FIG. . . . tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath. . .

DETDESC:

DETD(11)

"Muzzle loading" involves inserting the graft 1, already mounted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4. . .

DETDESC:

DETD(12)

"Muzzle . . . loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to. . . totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

DETDESC:

DETD(13)

The . . . over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially. . .

DETDESC:

DETD(14)

FIG. . . . iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted in the aorta 2 at the site of the aortic aneurysm 20.

DETDESC:

DETD(15)

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled,. . .

DETDESC:

DETD(18)

In . . . into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

DETDESC:

DETD(21)

All . . . devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1

during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including. . . of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially. . .

DETDESC:

DETD(22)

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

DETDESC:

DETD(23)

The . . . of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly. . . tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring. . . means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may. . . 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a. . . of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer. . .

DETDESC:

DETD(24)

FIG. . . . catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

DETDESC:

DETD(25)

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the. . .

DETDESC:

DETD(26)

The . . . open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy. . . sheath 4 is pulled back exposing the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass. . . tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the

graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn. . . . and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present). . . . past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26,. . .

DETDESC:

DETD(27)

Aortic . . . iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such. . . . contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends. . .

DETDESC:

DETD(28)

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

DETDESC:

DETD(30)

When . . . percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

DETDESC:

DETD(31)

Hereinafter described is a bifurcated endovascular graft 150 and the method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

DETDESC:

DETD(32)

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

DETDESC:

DETD(33)

All . . . the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted.

the silicone fill, the graft tissue can be inspected, or it may be irradiated UV or other bacteria-deterring radiation. Convex regions such as 22, 23. . .

DETDESC:

DETD(13)

There are several modes of application and use. A bag, prefilled with silicone may be applied to the graft area and then tied down, care being taken to properly tension all the ties. However, it is preferred to use. . . the upper surface of the bag will conform (pillow-out) different amounts in different area, yet the hydrostatic pressure on the graft tissue will be substantially equally uniformly distributed. Also, the amount of fill in the bag can be increased from time. . .

DETDESC:

DETD(14)

The . . . also has the property of being warm to the touch. It stores heat from the body and can insulate the graft area. By the same token, as it is a heat sink, it can absorb and dissipate excess heat from inflamed. . . only partly filled, and having limited expansibility, it conforms well to complex surface shapes when placed thereon. After application, the stent of this invention is examined on a regular basis, e.g. daily rounds, and the fill adjusted to keep the pressure on the graft tissue adequate. Due to the transparency, the stent need not be disturbed to view the graft tissue. After the graft has taken, the stent can be removed, by cutting or loosening the tie-overs or other securing means, and gently pulling it away from the. . . of the nature of the envelope material, dried tissue, scab material, and serous fluids do not stick to it. The stent can be reused, after sterilization, or disposed-of.

DETDESC:

DETD(15)

FIG. 2 shows an alternative configuration of the bag and method of retaining it in position over the graft area. Pad 1 overlies the graft tissue 7 to generally extend beyond the edge of the graft 6 as shown by the dotted outline of the bag edge 24. The bag is secured in place with an. . .

DETDESC:

DETD(16)

The central area of the mesh need not, but may also be adhesive coated so as to adhere to the upper surface of the bag. The apertures in the mesh permit inspection of the graft through the transparent bag envelope and silicone. A suitable mesh may be 3M "Steri-Strip" brand mesh skin closures. All materials adhering to skin tend to be insufficient for holding down a stent especially where surrounding areas are frequently in motion, e.g. the mandible or neck, or are covered by hair and/or sebaceous. . . glands. Where sufficient surrounding skin is present, e.g. on the trunk or an extremity, a small (4 or 6 cm) stent may be held down using tincture benzoin and wide adhesive tape.

DETDESC:

DETD(17)

It . . . be understood that the port assembly 5 may be omitted from a pad, where adjustment of the pressure on the graft is not required or desired. When using mesh as described above, a portion of the mesh may be cut away. . . and suitable holding of the pad is provided. If more edge holding power is required, a double-sided pressure sensitive adhesive tape may be placed on the skin under the open mesh edges 29 and 30 of the mesh and the mesh. . .

DETDESC:

DETD(19)

In . . . solid, flexible plastic marginal flap 31, which may be continuous, partial or intermittent, around the periphery of the bag. Adhesive tape may be secured to this flap and thence to the patient's skin surface. This flap is preferably of sufficient thickness. . .

DETDESC:

DETD(21)

FIG. . . . corrugations 43 through 47 therein to provide passages 48 through 51. This permits drainage, irrigation, or air exposure to the

graft tissue 7, to enhance it taking to the base tissue 52. The upper surface layer 53 of the bag is smooth in this embodiment. The graft tissue can be irrigated with medicament-containing solution, or drained of pus through these passages without disturbing the pad. The common. . . contact area 54 is large due to the pliable nature of the bag, thus providing for adequate pressure on the graft tissue yet retaining adequate passageway size.

DETDESC:

DETD(22)

The . . . as the plastic is not substantially permeable to either tissue fluids, irrigation solutions or the fill liquid, and has low adherence to tissue and serous fluid. Typically the bag wall may range from 0.005 to 0.040" in thickness, but should be. . .

DETDESC:

DETD(26)

As an alternative to silicone, water or water with a gelling agent, such as carboxymethyl cellulose, or a hydrolyzed 50/50 starch-polyacrylonitrile graft copolymer, may be used. One useful type of gelling agent is Flo-lok from Robinson Systems, the viscosity of which can. . .

DETDESC:

DETD(29)

Sterilization . . . cause the liquid (water, gel or silicone) to bubble, or residual ethylene oxide may cause adverse reaction in the sensitive graft tissue or base tissue.

CLAIMS:

CLMS(1)

I claim:

1. A skin graft pressure pad comprising in operative combination:
(a) means defining an enclosure for a liquid mass comprising a soft, easily deformable, transparent plastic bag and having a property of low adherence to tissue or serous fluids on at least one skin graft contact surface thereof;
(b) said enclosure means being pliable, freely conformable to variations in surface contour, and non-freestanding;
(c) at least one. . . and underlying tissue without substantial tissue necrosis;
(e) means for removably securing said enclosure containing said liquid in contact with said graft tissue; and
(f) said securing means being adapted to retain said pad in a predetermined position in direct continuous contact with said graft tissue to permit said liquid to transmit substantially uniform, growth-promoting pressure to said graft tissue without inducing substantial tissue necrosis.

CLAIMS:

CLMS(2)

2. . . . securing means comprises a plurality of flexible members disposed to permit visual observation of at least a portion of said graft tissue through said enclosure and said liquid.

CLAIMS:

CLMS(8)

8. Pressure pad as in claim 1 wherein the surface of said enclosure placed adjacent said graft is adapted to provide passages for fluid.

CLAIMS:

CLMS(12)

12. Method of applying uniform pressure to a skin graft comprising the steps of:
(a) selecting a partially full, liquid-containing pressure pad having a graft-tissue-facing surface larger than the area of said graft, said pressure pad comprising a soft, easily deformable, non-freestanding transparent plastic bag, and having a property of low adherence to tissue and serous fluids on at least one skin graft contact surface thereof;
(b) applying said pressure pad in free surface conformability to said area;

(c) maintaining said pad in direct continuous contact with said graft tissue with removable securing means; and
(d) maintaining the pressure pad of said pad on said graft area by adjusting the tightness of said securing means relative to the amount of said liquid in said pad;
thereby transmitting uniform pressure sufficient to promote contact between said graft tissue and underlying base tissue without substantial necrosis of said tissues.

CLAIMS:

CLMS(14)

14. Method as in claim 12 which includes the step of inspecting the progress of the taking of said graft by viewing the graft tissue through said pad.

CLAIMS:

CLMS(15)

15. Method as in claim 12 which includes the step of irrigating said graft tissue with a fluid introduced in spaces provided between said pad and an upper surface of said graft tissue.

cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

DETDESC:

DETD(34)

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251. . .

DETDESC:

DETD(35)

Grafts . . . may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

DETDESC:

DETD(36)

In . . . common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

DETDESC:

DETD(37)

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted. These lines or markers need be only imageable with. . . fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

DETDESC:

DETD(46)

The . . . control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGS. 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGS. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

DETDESC:

DETD(47)

As . . . FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches. . . suture 252 and 253 that pass along the wall of respective tubular extensions 246 and 247 to the junction with graft 206.

DETDESC:

DETD(48)

Alternatively, . . . caudal limb control suture 154 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256. . . and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when. . .

DETDESC:

DETD(49)

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter. . .

DETDESC:

DETD(50)

As . . . traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216. . .

DETDESC:

DETD(51)

As . . . used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 255 is also required on ipsilateral distal limb 213.

DETDESC:

DETD(54)

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

DETDESC:

DETD(55)

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external. . . sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath.. . . of the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of caudal stent 275.

DETDESC:

DETD(56)

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. Straightening device 130 is advanced over the distal limb control system onto the end of the distal. . . of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted .to the end of the graft to straighten any twists.

DETDESC:

DETD(57)

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132. . . maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the. . . reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

DETDESC:

DETD(62)

An . . . that guide insertion. Angiography will frequently have been

performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in. . .

DETDESC:

DETD(63)

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method depicted in FIGS. 48 and 49, a Dormier. . .

DETDESC:

DETD(65)

The . . . of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath 217 exposes the caudal limb control mechanisms and their. . . carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral. . .

DETDESC:

DETD(67)

Stents . . . required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used,. . . is usually necessary to maintain traction on the caudal limbs using the caudal limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

DETDESC:

DETD(68)

The . . . the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory,. . .

DETDESC:

DETD(70)

Prosthesis assembly 228 depicted in FIG. 43 includes bifurcated endovascular graft 206, main spring assembly 301, and limb spring assemblies 302 and 303 (not shown) positioned in respective stent boots 304 and 305. Main spring assembly 301, as well as prosthesis assembly 228, is contained in main container sheath 217 which is, for example, a polytetrafluoroethylene tube. Bifurcated endovascular graft 206 includes main body 250 with ipsilateral limb 213 and contralateral limb 210 extending therefrom and partially over the tops of respective stent boots 304 and 305.

DETDESC:

DETD(71)

As . . . through cranial orifice 207 and into bore 251 of the main body for radially expanding the main body of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285. Main spring assembly 301 expands from its compressed state, as shown in. . .

DETDESC:

DETD(72)

Transluminal arrangement 350 includes outer sheath 217 for containing main spring assembly 301 in a compressed state, stent boot sheath 304 for containing ipsilateral spring assembly in a compressed state; stent boot sheath 305 for containing contralateral spring assembly in

a compressed state; and main retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining prosthesis assembly 228 in the bifurcated lumen while the outer sheath is withdrawn from the prosthesis assembly releasing. . .

DETDESC:

DETD(75)

FIG. . . . spring assembly is attached to the inside of ipsilateral limb 213 via sutures 315 and 316 and is contained in stent boot sheath 304. When the prosthesis assembly is properly positioned about aneurysm 20, ipsilateral spring assembly 302 is released from. . . state to radially expand limb 213 and substantially conform the limb to the interior wall of common iliac artery 34. Stent boot sheath 304 forms a container for containing ipsilateral spring assembly 302 in a compressed state. Suture 314 is temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in the stent boot sheath during positioning of the prosthesis assembly in the bifurcated lumen. Suture 314 forms a release mechanism for releasing. . . limb 213 is properly positioned in common iliac artery 34. After suture 314 is detached from the ipsilateral spring assembly, stent boot 304 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state, ipsilateral spring assembly 302 radially expands graft limb 213 to substantially conform the limb on an interior wall of iliac artery lumen 286.

DETDESC:

DETD(76)

Stent boot 304 is a tubular container such as a sheath or short piece of polytetrafluoroethylene tube for containing ipsilateral spring assembly 302 therein in a compressed state. Ipsilateral spring assembly 302 is attached along its midsection to contralateral graft limb 213 inside limb bore 253 with sutures 315 and 316. Attachment sutures 315 and 316 are placed cranially from caudal orifice 208 to allow the caudal end of the graft limb to extend over the top of stent boot 304. Attachment sutures 314 and 317 are temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in stent boot 304. One end of attachment sutures 314 and 317 are tied around outer catheter 318 of the transluminal positioning. . . Attachment sutures 314 and 317 and inner catheter 319 form a retainer mechanism for retaining ipsilateral spring assembly 302 in stent boot 304. Connector sleeve 322 is a short length of tubing having apertures 320 and 319 formed laterally therethrough. The. . .

DETDESC:

DETD(77)

FIG. . . . partially sectioned side view of contralateral spring assembly 304, attached to the inside of contralateral limb 210, and contained in stent boot 305. Limb control catheter 255 is attached proximally to stent boot 305 and has suture 254 extending longitudinally through catheter lumen 306. Suture 254 is temporarily attached to contralateral spring assembly for retaining the spring assembly in the stent boot during positioning of the prosthesis assembly in the bifurcated lumen. Suture 254 forms a release mechanism for releasing the. . . contralateral limb 210 is positioned in common iliac artery 35. After suture 254 is detached from the contralateral spring assembly, stent boot 305 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state,. . . . an interior wall of iliac artery lumen 287. Limb control catheter 255 is a commercially available copolymer tube to which stent boot 305 is integrally formed or attached thereto, for example, using medical grade adhesive. Stent boot 305 is a tubular container such as a short piece of polytetrafluoroethylene tube for containing contralateral spring assembly 303 therein in a compressed state. Contralateral spring assembly 303 is attached along its midsection to contralateral graft limb 210 inside limb bore 255 with sutures 307 and 308. Attachment sutures 307 and 308 are placed cranially from caudal orifice 209 to allow the caudal end of the graft limb to extend over the top of stent boot 305. Contralateral spring assembly 303 can include one or more barbs for digging into the vessel wall and more. . .

DETDESC:

DETD(78)

FIG. 46 depicts a partially sectioned side view of stent boot 305 attached to control limb delivery catheter 255 which is positioned in longitudinal lumen 311 of contralateral limb straightening device 130. A plurality of longitudinal splines 312 is formed in the proximal end of stent boot 305 to match a corresponding plurality of splines 313 positioned around the distal end of straightening device lumen 311. The

mating splines engage each other to rotate the stent boot and contralateral limb for proper positioning within the common iliac artery. Markers are positioned in the graft limbs for radiographic imaging.

DETDESC:

DETD(79)

FIG. . . . 35. Main spring assembly 301 has been released from its compressed state and radially expanded main body 250 of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285 of the aorta. Similarly, ipsilateral spring assembly 302 has been released from its compressed state and elongated member 352 and radially expanded ipsilateral limb 213 of the graft to substantially conform the ipsilateral limb on an interior wall of lumen 286 of common iliac artery 34. Contralateral spring. . . been released from its compressed state and radially expanded contralateral limb 210 to substantially conform the contralateral limb of the graft on an interior wall of lumen 287 of common iliac artery 35. Control limb delivery catheter 255 and stent boot 305 have been withdrawn from the contralateral spring assembly allowing it to expand the contralateral limb of the graft.

DETDESC:

DETD(80)

The . . . sleeve 217 is withdrawn from the prosthesis assembly, and control limb delivery catheter 255 guides the contralateral limb of the graft into branch lumen 287 of iliac artery 35. The attachment sutures are released from the main, ipsilateral and contralateral spring assemblies positioning the prosthesis in the bifurcated lumen. Stent boots 304 and 305 are removed from their respective spring assemblies during withdrawal of retainer assembly 352 and control limb. . .

DETDESC:

DETD(81)

The . . . and that all changes and modifications that come within the scope of the claims are to be protected. In particular, stent boots 304 and 305 have been referred to as containers or sheaths and are typically formed from a thin polytetrafluoroethylene tube of material. The stent boots are either affixed to the outer catheter of the retainer assembly or slidable thereon. Similarly, stent boot 304 is attached using, for example, medical grade adhesive, are slidable at the end of the control delivery catheter.. . . of, for example, a semi-rigid polytetrafluoroethylene material for containing the prosthesis assembly therein. The spring assemblies are of the Gianturco Z-stent type as previously described with or without barbs for more securely affixing the prosthesis assembly to the wall of the bifurcated lumen. Any type of radially expanding spring assembly or stent is contemplated whether the spring assembly or stent is automatically expanded when released from a container or expanded with a dilator balloon and the like.

CLAIMS:

CLMS(1)

What . . .
containing in a compressed state a main spring assembly of a prosthesis assembly, said prosthesis assembly including a bifurcated endovascular graft having a main body and a first and a second limb extending therefrom, said main body including a main bore. . . said main bore and having a second caudal orifice, said main spring assembly radially expanding said main body of said graft to substantially conform said main body of said graft on an interior wall of a main lumen of a bifurcated lumen when said prosthesis assembly is positioned at a. . . state a first spring assembly of said prosthesis assembly, said first spring assembly radially expanding said first limb of said graft to substantially conform said first limb of said graft on an interior wall of the first branch lumen of the bifurcated lumen when said prosthesis assembly is positioned at. . . first spring assembly is released from said compressed state;
retainer means positioned in said main and said first bore of said graft for retaining said prosthesis assembly at the particular position in the bifurcated lumen while said main container means is withdrawn. . .

CLAIMS:

CLMS(10)

10. . . . and a second branch lumen communicating with and extending from the main lumen, said prosthesis assembly including a bifurcated endovascular graft having a main body and a first and a second limb

extending therefrom, said main body including a main bore. . . a second spring assembly each having a compressed state, said main spring assembly radially expanding said main body of said graft to substantially conform said main body of said graft on an interior wall of the main lumen when said prosthesis assembly is positioned at a particular position in the. . . main spring assembly is released from said compressed state, said first spring assembly radially expanding said first limb of said graft to substantially conform said first limb of said graft on an interior wall of the first branch lumen when said prosthesis assembly is positioned at the particular position in. . . first spring assembly is released from said compressed state, said second spring assembly radially expanding said second limb of said graft to substantially conform said second limb of said graft on an interior wall of the second branch lumen when said prosthesis assembly is positioned at a particular position in. . .
said second spring assembly in said compressed state;
main retainer means positioned in said main and said first bore of said graft for retaining said prosthesis assembly at the particular position in the bifurcated lumen while said main container means is withdrawn. . .

CLAIMS:

CLMS(17)

17. . . . and a second branch lumen communicating with and extending from the main lumen, said prosthesis assembly including a bifurcated endovascular graft having a main body and a first and a second limb extending therefrom, said main body including a main bore. . . limb including a second bore extending longitudinally therein, communicating with said main bore and having a second caudal orifice, said graft including a main spring assembly, a first spring assembly, and a second spring assembly each having a compressed state, said main spring assembly radially expanding said main body of said graft to substantially conform said main body of said graft on an interior wall of the main lumen when said prosthesis assembly is positioned at a particular position in the. . . main spring assembly is released from said compressed state, said first spring assembly radially expanding said first limb of said graft to substantially conform said first limb of said graft on an interior wall of the first branch lumen when said prosthesis assembly is positioned at the particular position in. . . first spring assembly is released from said compressed state, said second spring assembly radially expanding said second limb of said graft to substantially conform said second limb of said graft on an interior wall of the second branch lumen when said prosthesis assembly is positioned at a particular position in. . .
said second spring assembly in said compressed state;
an elongated member positioned in said main and said first bore of said graft;
main attachment means for temporarily attaching said main spring to said elongated member;
first attachment means for temporarily attaching said first spring. .

US PAT NO: 5,370,691 [IMAGE AVAILABLE] L1: 27 of 37
TITLE: Intravascular inflatable stent

ABSTRACT:
This invention is an intraluminal stent or graft suited for the noninvasive treatment of aneurysms, diseased blood vessels, and other bodily lumen. The stent is made up of polymeric tubing which is helically and tightly wound to produce a column having an open lumen from one end to the other. At the stent's distal end, the tubing is sealed. At the stent's proximal end, the stent is adapted to allow the introduction of fluid suitable for inflating the stent at the chosen vascular site. The stent coils adhere to each other or to one or more sizing strips which may be straight or helical in configuration, or the stent may be constructed to use both methodologies.

SUMMARY:

BSUM(2)

This invention is a intraluminal stent or graft suited for the noninvasive treatment of aneurysms, diseased blood vessels, and other bodily lumen. The stent is made up of polymeric tubing which is helically and tightly wound to produce a column having an open lumen from one end to the other. At the stent's distal end, the tubing is sealed. At the stent's proximal end, the stent is adapted to allow the introduction of fluid suitable for inflating the stent at the chosen vascular site. The stent coils adhere to each other or to one or more sizing strips which may be straight or helical in configuration, or the stent may be constructed to use both methodologies.

SUMMARY:

BSUM(4)

This invention is an inflatable stent which may be used within various portions of the body's vasculature.

SUMMARY:

BSUM(6)

There are a variety of different stent designs. By far most of them are made of metal wire or ribbon. For instance, WO 92/02,246, owned by Numed, Inc., shows a radially expandable stent made from fine wire formed into a serpentine ribbon wound into a cylindrical shape for introduction into a body vessel. The stent is placed within the vessel over a balloon which, when expanded, expands the stent in a radial fashion to support the wall of the vessel in the expanded configuration. This stent is said to be useful in the transluminar implantation of a stent for use in coronary angioplasty to prevent restenosis.

SUMMARY:

BSUM(7)

Other . . . things supported by a gridlike collection of metal or plastic wires. U.S. Pat. No. 4,800,882, to Gianturco, shows a wire stent made of a number of curved sections that are formed into a generally circular configuration.

SUMMARY:

BSUM(8)

None of these disclosures suggest a helically coiled inflatable stent such as is disclosed here.

SUMMARY:

BSUM(10)

This invention is an intralumenal stent or graft suited for the noninvasive treatment of aneurysms and diseased blood vessels and other bodily lumen needing such a prosthesis. The stent is made of a thin-wall highly flexible polymeric tube wound in a helical configuration. One end of the tube so wound is sealed and is typically placed distally of the catheter device used to introduce the stent into the human vasculature. The proximal end of the stent tubing is equipped with a one-way valve to allow introduction of suitable inflating fluid into the stent and to inflate it to its final size within the vascular site. The stent is in a collapsed or crushed form when initially introduced to the chosen site and grows in diameter as it. . .

SUMMARY:

BSUM(11)

The stent is produced by winding the flexible polymeric tubing about an appropriate mandrel and self-welding the device either among adjacent coils or by the use of other thermoplastic strips placed along the outer or inner surfaces of the resulting stent. The choice of the manner in which the stent is assembled results in a variety of stents having a variety of different, ultimately flexible, shapes.

DRAWING DESC:

DRWD(2)

FIG. 1A is an enlarged sideview of a variation of the inventive stent.

DRAWING DESC:

DRWD(3)

FIG. 1B is an enlarged sideview of a variation of the inlet one-way valve used in the inventive stent.

DRAWING DESC:

DRWD(4)

FIGS. 2, 3A, and 3B are enlarged side views of three variations of the inventive stent.

DRAWING DESC:

DRWD(6)

My convention in these drawings is to place the end of the stent which is proximal to the introduction site in the body to the left of the drawing and the distal end. . .

DETDESC:

DETD(2)

As has been noted above, this invention is an intravascular inflatable stent which is produced by winding polymeric tubing into a generally helical shape and treating the thus-wound helix in some fashion. . .

DETDESC:

DETD(4)

Many . . . been proposed as a treatment for aneurysms. However, because of the relative stiffness of the catheter configuration using both a stent and a balloon, access to the aneurysm site is difficult if not impossible. The irregular surface of most metallic stents. . . unlikely that the blood vessel from which the aneurysm arises is straight in the region of the aneurysm. Therefore, the stent ideally should have some flexibility along its axis so to conform to the curvature of the vessel at the aneurysm. . .

DETDESC:

DETD(5)

FIG. 1A is an enlargement of the basic configuration of the inventive stent device. The stent assembly, denoted as (100) in FIG. 1A, is a tightly, helically wound polymeric tubing (102) having a proximal end to. . . coil shape. The radiopaque markers (110) and (112) are optional, but practically are necessary to determine the position of the stent during its installation. Other methods of determining the position of the stent are, of course, known, and are useful here.

DETDESC:

DETD(6)

The polymer used in the tubing for this stent may be any of a variety of biocompatible polymers which are readily inflatable. For instance, thermoplastics such as high-density polyethylene,. . .

DETDESC:

DETD(8)

FIG. . . . is a close-up, partial sectional drawing of e one-way valve (104), as might be installed at the proximal end of stent (100). Tubing (102) is shown both in FIG. 1A and FIG. 1B. A small amount of a fusable thermoplastic is. . . is then melted within the tip of tubing (102) and a slit is formed between the two half-sections (112) which adhere to the inner surface of the wall of tubing (102). The shape of half-sections (113) ideally is such that a. . .

DETDESC:

DETD(9)

FIG. . . . shows a variation (200) of the device portrayed in FIG. 1. All of the components described above with relation to stent (100) in FIG. 1A are also found in this variation. The difference lies in the use of a sizing strip (202) along the axis of the stent and placed inside the lumen or outside on the outer lumen diameter. This sizing strip (202) provides a reasonably constant length of polymeric material which adheres to the coils along the sizing strip's length and keeps them from unwrapping.

DETDESC:

DETD(10)

The FIG. 2 stent variation (200) is made in a similar way to that described in relation to FIG. 1. However, after the extruded. . . strip of nonirradiated polyethylene is laid on the mandrel (if an inside sizing strip is desired) or outside the wound stent (if an outer sizing strip is desired). More than one sizing strip may be used and, depending upon their intended use and the nature of the vascular site into which the stent is to be placed, may be placed in a variety of sites. The whole set-up is then heated only to. . .

DETDESC:

DETD(11)

Use of a stent having a single sizing strip on one side may result in a stent having the ability to bend very far in one direction to close the neck of an aneurysm on the inside of a radius of a bending artery. The other side of the nonadhering side may open as the stent is inflated. Said another way, the stent would be closed on the inside of the turn and the stent would be open on the outer side of the bending radius.

DETDESC:

DETD(12)

FIG. . . . of the components found in the FIG. 1A device (100). The sizing strips (302) are placed helically about the wound stent prior to moderate heat treatment. In this way, the stent, while partially flexible, is somewhat less so because of the presence of the helical sizing strips. The variations shown in FIG. 2 at 3 may utilize a single sizing strip inside or outside of the stent lumen or outside diameter, or multiple strips in or out. In especially troublesome situations where a relatively stiff stent is desirable, stents having criss-crossing sizing strips may be employed.

DETDESC:

DETD(13)

FIG. . . . in which the sizing strips (302) cross in order to provide the least amount of compliance for the resulting inventive stent.

DETDESC:

DETD(14)

The stent may be suitably reduced in size for introduction using a catheter in a variety of ways. The result of one. . . . mandrel or other suitably strong round surface and collapsed or rolled so as to reduce the outer diameter of the stent and thus maintain the presence of an inner false lumen (402) after the completion of the crushing operation. This allows the stent to be used in a catheter with a guidewire or other device which must pass through the interior of the stent during its residency in the catheter.

DETDESC:

DETD(15)

FIG. 4B shows a similar reduced configuration in which the stent of any of the configurations above is folded about a mandrel (404) (which mandrel is later removed) to form a. . . . other similar materials which are generally unaffected by moderate heat treatment and thus are removable. The wrapped, crushed, or folded stent with included mandrel is often placed within another forming means such as TEFLON tubing and maintained at moderately elevated temperature, e.g., 125.degree. F., for a short period of time to allow the folded or crushed stent to temporarily maintain the shape shown in the figures. This allows the folded stent to be introduced through the catheter lumen with relative ease.

DETDESC:

DETD(16)

The device described herein may be used in the following manner. The inflatable stent may be attached to the tip of an infusion catheter which may be then or later filled with a medium.. . . collapsed device. The assembly is then threaded into a guide catheter. The guidewire is then used to maneuver the collapsed stent assembly to the desired vascular site. The device is then pressurized to lock into position, and the catheters are then removed, thereby leaving the device in place. The stent may be filled with radiopaque contrast material to provide radiopacity to the stent. The stent alternatively may be filled with a quick-curing adhesive or gel such as HEMA having adequate curing time, mixed with a tantalum powder or the like for radiopacity. This mixture, once cured, will provide the stent with exceptional long-term patency.

CLAIMS:

CLMS(1)

I claim as my invention:

1. An inflatable stent comprising tightly, helically wound polymeric tubing forming tubing turns and having a proximal tubing end and a distal

tubing end, forming a hollow column having an outer column diameter and an inner lumen extending along a stent axis from a proximal stent end to a distal stent end and having a lumen diameter, the distal tubing end being sealed and the proximal tubing end being adapted to accept an inflating fluid and having at least one flexible polymeric sizing strip laid against and adherent to the polymeric tubing from the region with the proximal stent end to the region of the distal stent end and where said at least one flexible polymeric sizing strip has a softening point below the softening point of. . .

CLAIMS:

CLMS(2)

2. The inflatable stent of claim 1 where the proximal tubing end adapted to accept an inflating fluid comprises a one-way valve.

CLAIMS:

CLMS(3)

3. The inflatable stent of claim 2 where the one-way valve comprises a plug of an elastomer having a slit therethrough which closes upon. . .

CLAIMS:

CLMS(4)

4. The inflatable stent of claim 1 where the tightly, helically wound polymeric tubing turns adjacently adhere to each other.

CLAIMS:

CLMS(5)

5. The inflatable stent of claim 4 where the turns are thermally welded to each other.

CLAIMS:

CLMS(6)

6. The inflatable stent of claim 1 where the one or more sizing strips are positioned generally parallel to the stent axis.

CLAIMS:

CLMS(7)

7. The inflatable stent of claim 1 where the one or more sizing strips are generally located in a spiral about the outer column. . .

CLAIMS:

CLMS(8)

8. The inflatable stent of claim 1 where the polymer of the polymeric tubing is selected from polyethylene, polypropylene, their interpolymers and block copolymers;. . .

CLAIMS:

CLMS(9)

9. The inflatable stent of claim 1 where the sizing strips comprise polyethelene.

CLAIMS:

CLMS(10)

10. The inflatable stent of claim 1 which has been collapsed to form a collapsed stent having a reduced outer column diameter and having a false lumen extending from the distal stent end to the proximal stent end.

CLAIMS:

CLMS(11)

11. The inflatable stent of claim 1 also comprising at least one radiopaque marker located at at least one of the proximal stent end and the distal stent end.

US PAT NO: 5,274,074 [IMAGE AVAILABLE] L1: 28 of 37

SUMMARY:

BSUM(20)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

DETDESC:

DETD(4)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

DETDESC:

DETD(5)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

DETDESC:

DETD(8)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular graft; striated fibers may be used in the fabrication of devices as ligament or tendon prostheses to encourage certain alignment of. . .

DETDESC:

DETD(15)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

DETDESC:

DETD(16)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

DETDESC:

DETD(65)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

DETDESC:

DETD(66)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(211)

Completely Bioresorbable Graft-Fabrication

DETDESC:

DETD(220)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(221)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(222)

A . . . coating polymer, e.g., the random copolymer of 91% TMC--9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bio-resorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(228)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(233)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(245)

Fabrication of Rod and Ribbon as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(246)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(247)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(248)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(249)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(285)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(290)

Cloth . . . various bioresorbable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(301)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(302)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(308)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,256,764 [IMAGE AVAILABLE] L1: 29 of 37

SUMMARY:

BSUM(19)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

SUMMARY:

BSUM(34)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite

device having a body which is composed of a. . .

SUMMARY:

BSUM(35)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(38)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular graft; striated fibers may be used in the fabrication of devices as ligament or tendon prosthesis to encourage certain alignment of. . .

SUMMARY:

BSUM(45)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

SUMMARY:

BSUM(46)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

SUMMARY:

BSUM(90)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

SUMMARY:

BSUM(91)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(140)

Completely Bioresorbable Graft-Fabrication

DETDESC:

DETD(149)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(150)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(151)

A . . . coating polymer, e.g., the random copolymer of 91% TMC-9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(158)

For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(163)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(175)

Fabrication of Rod and Ribbon as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(176)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(177)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(178)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(179)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(215)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(220)

Cloth . . . various bioresorable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(231)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(232)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(238)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,185,408 [IMAGE AVAILABLE] L1: 30 of 37

SUMMARY:

BSUM(27)

The . . . casting, solution extrusion, gel extrusion and the like, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The devices of this invention may also be fibrous devices constructed of woven or non-woven fabric. . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft coated with one or more copolymers of this invention.

SUMMARY:

BSUM(29)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable copolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing copolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(46)

While . . . carbonate and lactide. In other situations where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure II are. . .

DETDESC:

DETD(22)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(25)

3. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(26)

4. . . . coating polymer, e.g., the random copolymer of 91% TMC-9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(33)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(35)

Similar to Example 6, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(72)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(84)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(85)

An . . . at around 200.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced is stored in a Class 100 laminar flow hood for over 48 hrs., before it is cold drawn. The. . .

DETDESC:

DETD(91)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

CLAIMS:

CLMS(1)

What is claimed is:

1. A prosthetic tubular graft for surgical implantation in animals comprising a tube which is formed totally or in part of one or more copolymers. . .

CLAIMS:

CLMS(2)

2. A prosthetic tubular graft according to claim 1 wherein n is 1 to about 3.

CLAIMS:

CLMS(3)

3. A prosthetic tubular graft according to claim 1 wherein R.sub.1 and R.sub.2 are the same or different and are hydrogen or alkyl.

CLAIMS:

CLMS(4)

4. A prosthetic tubular graft according to claim 3 wherein R.sub.1 and R.sub.2 are the same or different and are hydrogen or alkyl having from. . .

CLAIMS:

CLMS(5)

5. A prosthetic tubular graft according to claim 4 wherein the recurring monomeric units of the Structure II are derived from a lactide.

CLAIMS:

CLMS(6)

6. A prosthetic tubular graft according to claim 5 wherein the recurring monomeric units of the Structure II are derived from d-lactide, l-lactide or d,l-lactide.

CLAIMS:

CLMS(7)

7. A prosthetic tubular graft according to claim 1 wherein the amount of the recurring monomeric units of the Structure I in said copolymer is. . .

CLAIMS:

CLMS(8)

8. A prosthetic tubular graft according to claim 7 wherein said amount is at least about 85 wt %.

CLAIMS:

CLMS(9)

9. A prosthetic tubular graft according to claim 8 wherein said amount is from about 85 wt % to about 99 wt %.

CLAIMS:

CLMS(10)

10. A prosthetic tubular graft according to claim 9 wherein said amount is from about 90 wt % to about 99 wt %.

CLAIMS:

CLMS(11)

11. A prosthetic tubular graft according to claim 1 wherein said copolymer is a random copolymer.

CLAIMS:

CLMS(12)

12. A prosthetic tubular graft according to claim 1 wherein said copolymer is a block copolymer.

CLAIMS:

CLMS(13)

13. A prosthetic tubular graft according to claim 12 wherein said block copolymer has an AB or an ABA structure wherein A is a block. . .

CLAIMS:

CLMS(14)

14. A prosthetic tubular graft according to claim 13 wherein said block copolymer is a block copolymer of the structure ABA.

CLAIMS:

CLMS(15)

15. A prosthetic tubular graft according to claim 1 wherein said graft is fabricated wholly from one or more of said copolymers.

CLAIMS:

CLMS(16)

16. A prosthetic tubular graft according to claim 1 wherein said tube is an extruded tube formed of one or more of said copolymers or. . .

CLAIMS:

CLMS(17)

17. A prosthetic tubular graft according to claim 1 wherein said graft is formed partially from one or more of said copolymers.

CLAIMS:

CLMS(18)

18. A prosthetic tubular graft according to claim 17 wherein said graft comprises a tube coated with one or more of said copolymers, said tube formed from a biodurable polymeric material or. . .

CLAIMS:

CLMS(19)

19. A prosthetic tubular graft according to claim 18 wherein said tube is an extruded tube or is a woven or non-woven fabric tube.

CLAIMS:

CLMS(20)

20. A prosthetic tubular graft according to claim 19 wherein said tube is formed of a biodurable polymeric material.

CLAIMS:

CLMS(21)

21. A prosthetic tubular graft according to claim 13 wherein said tube is formed of a bioresorbable polymeric material.

CLAIMS:

CLMS(22)

22. A prosthetic tubular graft for surgical implantation in animals selected from the group consisting of vascular grafts, nerve channels, and wound closing or covering. . .

CLAIMS:

CLMS(23)

23. A prosthetic tubular graft according to claim 22 wherein the recurring monomeric units of the Structure II are derived from lactide.

CLAIMS:

CLMS(24)

24. A prosthetic tubular graft according to claim 23 wherein the amount of recurring units of the Structure II in said copolymer is at least. . .

CLAIMS:

CLMS(25)

25. A prosthetic tubular graft according to claim 24 which is a vascular graft.

CLAIMS:

CLMS(26)

26. A prosthetic tubular graft according to claim 24 which is a wound closing or covering device.

CLAIMS:

CLMS(27)

27. A prosthetic tubular graft according to claim 24 which is a nerve channel.

US PAT NO: 5,152,781 [IMAGE AVAILABLE] L1: 31 of 37

SUMMARY:

BSUM(19)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

DETDESC:

DETD(4)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

DETDESC:

DETD(5)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

DETDESC:

DETD(8)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular graft; striated fibers may be used in the fabrication of devices as ligament or tendon prosthesis to encourage certain alignment of. . .

DETDESC:

DETD(15)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

DETDESC:

DETD(16)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

DETDESC:

DETD(60)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

DETDESC:

DETD(61)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(206)

Completely Bioresorbable Graft-Fabrication:

DETDESC:

DETD(215)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(216)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(217)

A . . . coating polymer, e.g., the random copolymer of 91% TMC-9% 1-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bio-resorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(223)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(228)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(240)

FABRICATION OF ROD AND RIBBON AS EXTERNAL SUPPORT FOR DACRON OR BIORESORBABLE VASCULAR GRAFTS

DETDESC:

DETD(241)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U0004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(242)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(243)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(244)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(280)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(285)

cloth . . . various bioresorbable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(297)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(298)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(304)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,145,945 [IMAGE AVAILABLE] L1: 32 of 37

SUMMARY:

BSUM(20)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

SUMMARY:

BSUM(35)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

SUMMARY:

BSUM(36)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(39)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular graft; striated fibers may be used in the fabrication of devices as ligament or tendon prosthesis to encourage certain alignment of. . .

SUMMARY:

BSUM(46)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

SUMMARY:

BSUM(47)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

SUMMARY:

BSUM(96)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

SUMMARY:

BSUM(97)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(136)

Completely Bioresorbable Graft-Fabrication

DETDESC:

DETD(145)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(146)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(147)

A . . . coating polymer, e.g., the random copolymer of 91% TMC--9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(153)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(158)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(170)

Fabrication of Rod and Ribbon as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(171)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(172)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(173)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(174)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(210)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(215)

Cloth . . . various bioresorbable fibers can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medical-grade silicone film can be. . .

DETDESC:

DETD(227)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(228)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(234)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 5,108,407 [IMAGE AVAILABLE] L1: 33 of 37

SUMMARY:

BSUM(10)

Heating of the metal cap to cause coagulation softens the hot melt glue, and if tension were applied to the optic fiber, the distal or free end thereof might become dislocated from the. . . the aneurysm, a second burst of laser energy is transmitted through the optic fiber, sufficient to soften the hot melt glue, and to facilitate withdrawal of the optic fiber end therefrom. The second laser burst, for removal of the optic fiber,. . .

SUMMARY:

BSUM(11)

U.S. Pat. No. 4,795,458 teaches a stent made of shape memory alloy in either tape or wire form for vascular implantation to prevent restenosis after balloon angioplasty. The coil has a diameter less than that. . .

SUMMARY:

BSUM(12)

It . . . 4,503,569 employs a coil of shape memory alloy which is transluminally positioned to serve as a prosthesis for an endovascular graft. A hot saline solution, passed through the introducer catheter, heats the coil to its transition temperature causing expansion of the. . .

SUMMARY:

BSUM(15)

U.S. . . . wire filter is passed through the catheter with a guide wire feeder device. U.S. Pat. No. 4,300,244 discloses a cardiovascular graft using a carbon-coated tightly wound spring to provide a biocompatible interior surface which provides an unobstructed passageway for blood flow.. . .

US PAT NO: 5,066,772 [IMAGE AVAILABLE] L1: 34 of 37

SUMMARY:

BSUM(28)

The . . . casting, solution extrusion, gel extrusion and the like, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The devices of this invention may also be fibrous devices constructed of woven or non-woven fabric. . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft coated with one or more copolymers of this invention.

SUMMARY:

BSUM(30)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable copolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing copolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(47)

While . . . carbonate and lactide. In other situations where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure II are. . .

DETDESC:

DETD(22)

Completely Bioresorbable Crimped and Coated Graft:

DETDESC:

DETD(25)

3. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(26)

4. . . . coating polymer, e.g., the random copolymer of 91% TMC--9% 1-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(33)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure used to diminish bleeding. . .

DETDESC:

DETD(35)

Similar to Example 6, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(72)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(85)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(86)

An . . . at around 200.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced is stored in a Class 100 laminar flow hood for over 48 hrs., before it is cold drawn. The. . .

DETDESC:

DETD(92)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

CLAIMS:

CLMS(16)

16. A medical device according to claim 1 which is a vascular graft.

US PAT NO: 4,920,203 [IMAGE AVAILABLE] L1: 35 of 37

SUMMARY:

BSUM(19)

The . . . pliable materials having intermediate or slower rates of bioresorbability which can be fabricated into devices such as nerve channels, vascular graft body, sutures, tendon or ligament replacements and the like, where elasticity, strength, pliability and an intermediate or slow rate of. . .

SUMMARY:

BSUM(34)

The . . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft. The device may be a solid part which has been fabricated into the desired shape using a conventional technique for. . . thermoplastics, such as extrusion, molding and solution casting, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The device may also be a composite device having a body which is composed of a. . .

SUMMARY:

BSUM(35)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable biopolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing biopolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(38)

The . . . intended use. For example, smooth fibers having a solid cross-section may be important for fabrication of devices such as vascular graft; striated fibers may be used in the fabrication of devices as ligament or tendon prosthesis to encourage certain alignment of. . .

SUMMARY:

BSUM(45)

Particularly . . . formed from fabrics and the like, using conventional techniques as for example extrusion, weaving, knitting and the like. For vascular graft applications, the internal diameter commonly found useful is in the range of from about 1.0 mm to about 30 mm.

SUMMARY:

BSUM(46)

In the preferred embodiments of the invention, especially for vascular graft applications, the device is pre-treated to provide a more complaint prostheses. Any conventional method can be used. One preferred pretreatment. . . . mean diameter of the grafts. Crimping as such can be achieved by this method for the bioresorbable grafts. The vascular graft is preferably coated with a bioresorbable biopolymer of this invention (especially the internal surface) to improve graft patency. The coating is usually an amorphous bioresorbable biopolymer or biopolymer blend which has some solubility in a solvent which is a non-solvent for the polymer or biopolymers forming the graft body. The coating may be applied to the graft by dissolving the coating biopolymer or biopolymer blend in a solvent which is a non-solvent for the graft polymer or biopolymer and then dipping the graft body into the solution.

SUMMARY:

BSUM(91)

While . . . a soft, pliable and relatively fast bioresorbing copolymer is required as for example as a coating on a Dacron vascular graft, monomeric units such as those of the Structure III where n is 1 to 3 and R.sub.5 and R.sub.6 are. . .

SUMMARY:

BSUM(92)

In other situation where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure III where. . .

DETDESC:

DETD(137)

Completely Bioresorbable Graft-Fabrication:

DETDESC:

DETD(146)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(147)

1. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(148)

A . . . e.g., the random copolymer of 91% TMC - 9% 1-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(154)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure

used to diminish bleeding. . .

DETDESC:

DETD(159)

Similar to Example 32, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(171)

Fabrication of Rod and Ribbon as External Support For Dacron or Bioresorbable Vascular Grafts

DETDESC:

DETD(172)

1. . . . stretched six-fold and then was attached to a 8 cm long piece of straight Weavenit knitted Dacron 4 mm vascular graft (Meadox Medical Inc. Catalog No. 07U004, Lot No. 237012) in a spiral fashion and fastened every 20.degree. with 7-0 Prolene. . . laminar flow hood to air dry. A clean and dry 4 mm OD pyrex glass rod was inserted into the graft so that a good contact would be established between the knitted fabric and the external spiral support to enhance adhesion. . . total of eight dips were applied before the total weight gain reached 10%. The Prolene suture was later removed. The graft did not kink or collapse upon bending.

DETDESC:

DETD(173)

2. . . . set. The final size was 2.0 mm.times.0.5 mm. It was similarly attached to a 4 mm straight Weavenit Dacron vascular graft. The graft was also coated as before. The benefit of not kinking and collapsing was also achieved.

DETDESC:

DETD(174)

3. . . . in a similar fashion but the die size was changed to 4.0 mm.times.0.50 mm. After aging and stretching, the final ribbon size was 2.0 mm.times.0.25 mm. It was attached to 4 mm diameter straight Weavenit Dacron vascular graft in the same manner and coated as before. The prosthesis stayed open when bent, and kinking or collapsing was avoided.

DETDESC:

DETD(175)

4. Similarly, the rod or ribbon can be applied to a completely bioresorbable graft since the bioresorbable yarn used to fabricate the totally bioresorbable graft was not affected by the dimethyl sulfoxide solvent.

DETDESC:

DETD(211)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(216)

Cloth . . . various bioresorbable fibres can be used. This includes woven and non-woven such as mesh, felt, cloth, knit, etc. After cleaning, adherence of these materials to a selective barrier is desirable. For example, a thin layer of medicalgrade silicone film can be. . .

DETDESC:

DETD(227)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(228)

An . . . extruded at 190.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced was stored in a Class 100 laminar flow hood for 48 hrs., before it was cold drawn to give. . .

DETDESC:

DETD(234)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 4,916,193 [IMAGE AVAILABLE] L1: 36 of 37

SUMMARY:

BSUM(27)

The . . . casting, solution extrusion, gel extrusion and the like, such as an extruded hollow tubular nerve channel or extruded hollow vascular graft, or a stent for use in angioplasty. The devices of this invention may also be fibrous devices constructed of woven or non-woven fabric. . . means, which fabrics may then be used to fabricate a device, such as a wound cover, gauze, and a vascular graft coated with one or more copolymers of this invention.

SUMMARY:

BSUM(29)

The . . . and/or biodegradeability or which is even relatively biodurable. On the other hand, another device of this invention is a vascular graft composed of a fabric composed of a relatively biodurable material such as Dacron or a bioresorbable copolymer having a relatively slow rate of bioresorption coated with a relatively fast bioresorbing copolymer, especially in the inside of the graft. The use of the coating having fast rate of bioresorption provides for a regenerated blood vessel having a high degree. . .

SUMMARY:

BSUM(45)

While . . . carbonate and lactide. In other situations where toughness and a slower bioresorption rate is desired as for example in a stent, a tendon or ligament replacement device, orthopedic plates and pins, monomeric units such as those of the Structure II are. . .

DETDESC:

DETD(22)

Completely Bioresorbable Crimped and Coated Graft

DETDESC:

DETD(25)

3. . . . (U.S. Pat. No. 3,337,673) was used. Thus, the spacer was provided by a cotton string helically wound on the fabric graft body with a glass mandrel inserted into the lumen. Crimp-shape was formed by slowly forcing the two ends of the graft towards the middle. The crimping can be set to as small as 0.5 millimeter up and 0.1 to 0.2 mm. . .

DETDESC:

DETD(26)

4. . . . coating polymer, e.g., the random copolymer of 91% TMC-9% l-lactide, was made with solvent dimethyl sulfoxide (DMSO). The clean bioresorbable graft was dipped into said solution six dips, inverting between each dip, to yield a 10% weight gain. In another example,. . .

DETDESC:

DETD(33)

Control Experiment. For comparison, the same procedure was performed with the Sauvage Bionit graft as received without coating. However, the grafts were preclotted just prior to insertion, a standard procedure

used to diminish bleeding. . .

DETDESC:

DETD(35)

Similar to Example 6, four similar eight centimeter long six millimeter diameter Sauvage Bionit vascular graft with the same coating polymer but 50% weight gain were implanted in two adult sheep as bilateral carotid replacements. One. . .

DETDESC:

DETD(72)

Similarly, . . . dip coating. Dip coating twice allowed a weight gain of 3% which was sufficient to have most of the filaments adhere together but the prothesis was not coated too heavily to become rigid and kink. The two ends were also coated. . .

DETDESC:

DETD(84)

Fabrication of Rod and Ribbon as Internal Support in Conjunction with Balloon Angioplasty

DETDESC:

DETD(85)

An . . . at around 200.degree. C. in the modified Instron extruder, with either a round or a rectangular die. The rod or ribbon produced is stored in a Class 100 laminar flow hood for over 48 hrs., before it is cold drawn. The. . .

DETDESC:

DETD(91)

Similarly, . . . C. oven, the DMSO coating solution was added onto the film while still hot. The solution had a tendancy to adhere unevenly; however, with care in spreading the solution, and subjecting the system to heating in the oven, and repeating the. . .

US PAT NO: 4,202,331 [IMAGE AVAILABLE] L1: 37 of 37
TITLE: Skin graft pressure pad

ABSTRACT:
Apparatus and method for applying more uniform pressure to an area of skin that is undergoing a skin graft. Pressure pad comprises a soft, pliable, transparent plastic envelope fillable with a viscous, transparent liquid to provide even distribution of pressure while permitting visual inspection of, and transmission of radiation to bathe the skin graft area, without removal of the pressure pad. Pad is removably securable to the area adjacent the graft by a variety of securing means. In one embodiment the graft area contact surface of the pad is specially adapted to permit air to contact the graft tissue. Pad is sterilizable, and the envelope is of a nature that drying tissue and serous fluid will not adhere to it. Pad preferably has a port permitting precise control of the amount of liquid fill (preferably silicone) in the. . . introduced or withdrawn by means of a syringe. In turn, this permits precise control of the pressure applied to the graft tissue. Pad structure is adapted to be highly conformable to irregular surface contours insuring full contact and uniform hydrostatic pressure on graft tissue.

SUMMARY:

BSUM(2)

This invention relates to skin grafting apparatus and methods, and more particularly to the problem of promoting contact between graft tissue and host tissue so that the graft will take with minimum necrosis. Special liquid-fillable pressure pads and methods provide necessary pressure, are disposable or non-disposable and sterilizable,. . .

SUMMARY:

BSUM(4)

A . . . tissue, that portion can die within 48 hours. The loss area must then cover itself over by ingrowth from surrounding graft tissue that has taken. The possibilities of unnecessary scarring, and infection increase, and the entire grafting process is lengthened. While. . .

SUMMARY:

BSUM(5)

The most common and almost universal present-day technique of promoting uniform skin graft contact consists of tying a stent, made of left-over pieces of gauze found on the nurse's Mayo stand, over the area being grafted. As these are not designed for the purpose and ill serve it, surgeons wet the stent before cutting it to the shape of the grafted area. Others try wadded cotton wet with water or mineral oil. For a convex area, some surgeons use very stiff, large-mesh gauze. The make-shift stent is then tied over by sutures along the margin of the graft. This is a time-consuming procedure, and results in a spider web of dozens of ties along the ends of the. . .

SUMMARY:

BSUM(6)

These . . . apply even pressure in small areas. The sutures usually loosen after a few days, lessening the needed pressure on the graft. Of course, excess pressure will prevent proper circulation of the graft tissue from the host and will result in slow grafting or tissue necrosis. This is typically the case in raised. . . e.g. the dorsum of the nose, where uneven, excess pressure causes sloughing. Likewise, in many instances an edge of a graft is lost because the make-shift stent did not apply even pressure at the margin.

SUMMARY:

BSUM(7)

Between the second and fifth post-operative day, some surgeons disrupt a portion of the stent to view the viability of the graft tissue or the accumulation of pus. Since the stent is opaque and only one edge is viewed, surgeons presently conclude by inference that if the one corner is good, the whole graft has survived. This often proves a false inference due to the nature of the gauze stents and tying procedures.

SUMMARY:

BSUM(8)

Another serious problem is adherence of graft tissue to the stents. Numerous materials, such as saline-soaked or mineral oil-soaked gauze, "Xeroform" brand gauze, Owin's gauze, Bacitracin or Neomycin-impregnated 4.times.4's and "Adaptic" brand sheets, have been placed over the graft to attempt to prevent adherence and tearing-off of the graft at the time of stent removal. No one present method is perfectly free of this adherence problem, and a great deal of time and soaking of stents is employed to aid their removal.

SUMMARY:

BSUM(9)

In . . . 3,171,410 discloses an oval shaped (in cross-section) inflatable bladder having a gauze pad on the side facing the wound. Pressure-sensitive tape passes over the other side of the bladder and extends therebeyond to secure the bladder to the recipient (injury) site.. . .

SUMMARY:

BSUM(10)

Lehmann . . . to furnish pressure dressings for Wolfe grafts. These bags are placed over a sterile vessel (probably a gauze or cotton stent) covering the graft, fixed lightly with either a gauze or lint bandage supported by adhesive tape, and inflated to a pressure of 33 mm Hg. On the 4th day the bag is deflated and the dressing opened to care for blebs or small pustules in the graft. Care must be taken not to disturb the graft in any way. The entire dressing is replaced. One design is for a nose bag, which includes an upper and lower tube for passing hot or cold water therethrough, thereby heating or cooling the graft. Schwager, R. G., and Imber, G. in "Inflatable Splint To Immobilize Extremities After Skin Grafting," Plastic and Reconstructive Surgery J.,. . . stuck to the surrounding skin by collodion. An elastic bandage and the air-inflatable spint are then applied over the gauze stent. The splint extends along the entire extremity, well beyond the graft area. The dressing is changed after 48 hours. If the splint remains in place for a much longer period, which. . .

SUMMARY:

BSUM(11)

Accordingly there is a need for improved methods and apparatus for applying controllable pressure uniformly over the entire graft area, even where irregular in shape or elevation, which permits easy inspection of the graft while healing is in process, and reduces the adherence problem.

SUMMARY:

BSUM(15)

It is another object to provide a transparent, fluid-filled skin graft pressure pad which permits continuous observation during healing without disturbing the pad or the graft tissue.

SUMMARY:

BSUM(16)

It is another object to provide a skin graft pressure pad that can be filled in any desired amount with a viscous clear fluid, the mass and fluid nature. . . . on the margins and irregular areas, while the transparent nature of the pad permits visual examination or irradiation of the graft during healing.

SUMMARY:

BSUM(17)

It is another object to provide a means of (daily if necessary) injecting more fluid into the stent from time to time as required to increase pressure on the graft as necessary if and when the tie-down sutures loosen with time.

SUMMARY:

BSUM(18)

It is another object to provide a surface against which the skin graft will not adhere and thus not be torn, shredded or loosened while the stent is being removed.

SUMMARY:

BSUM(19)

It . . . need of manufacturing a large number of stents of differing sizes. p It is another object to provide a skin graft pressure pad specially adapted with means to permit air access to the graft tissue while healing.

SUMMARY:

BSUM(20)

It is another object to provide a skin graft pressure pad specially adapted with means for securing the pad in place over the grafted tissue area.

SUMMARY:

BSUM(21)

It is another object to provide a skin graft pressure pad that is sterilizable, reuseable, and rapid to apply.

DRAWING DESC:

DRWD(6)

FIG. 4 is a section view of a pressure pad of this invention showing the graft-facing surface of the pad having a surface adapted to provide air passageways to the graft.

DETDESC:

DETD(2)

The . . . material. The bag or envelope shape and size are preselected to be larger when filled than the area of the graft tissue so that pressure is applied by the bag uniformly across and to the edges of the graft. The transparency and clarity of the bag and liquid filling permits continuous inspection of the graft tissue during healing without removal of the pressure bag or disturbing the graft. The high viscosity and high index of refraction of the silicone (as compared to air), and generally oval cross sectional shape of the bag provides a degree of magnification of the graft tissue

thereunder which aids inspection of the tissue. The clarity and transparency permit light, UV or IR irradiation of the graft tissue to promote healing.

DETDESC:

DETD(3)

The bag plastic is preferably of limited stretchability, and is of a material that has low adherability to graft tissue, insipated serous solutions, scab forming material and the like. A polyvinyl chloride or silicone polymer film material is suitable.. . . bag is preferably only partially filled, so that the bottom side will conform to the curve and shape of the graft tissue. The bag fill can be increased from time to time as necessary to maintain the proper pressure, e.g. where. . .

DETDESC:

DETD(4)

The mass of the silicone filling material provides adequate grating pressure, and the precise total weight applied to the graft area can be controlled by adding or withdrawing silicone from the bag as desired. Overfilling is preferably avoided as this causes the bag to become more spherical, resulting in lifting the bag surface away from the edge of the graft area, and increasing undesirable lateral momentum upon body movements.

DETDESC:

DETD(5)

The . . . pressure pad is capable of absorbing blows, shocks and changes of direction which could cause slippage or shearing of the graft with respect to the base tissue. In addition, the mass of the bag serves both "alert" and "resistance" functions. The mass alerts or reminds the patient that the graft must be guarded. For example, for a graft on an extremity, the presence of the mass or weight sensed by the patient will tend to continuously make the patient more aware of the graft; the patient will move his or her limbs more carefully. The "resistance" function occurs by virtue of the patient having. . .

DETDESC:

DETD(6)

The bottom, or graft side, surface of the pad may be smoothly corrugated, quilted or otherwise configured to provide air or fluid passageways across the graft area from the edge of the pad.

DETDESC:

DETD(7)

The pad may be secured over the graft area by a variety of means and methods. In one embodiment, filaments may be sutured to the skin exteriorly of the graft area and passed over the bag to secure it in place. In another, preferred, embodiment, the bag includes one or. . . securing the bag in position. These means can be tied together around a limb, or may be secured by adhesive tape, or themselves have one or more adhesive surfaces permitting adherence to the skin or others of the tie means.

DETDESC:

DETD(10)

FIG. . . . of silicone through port 5. The bag assembly is shown of a size extending beyond the periphery 6 of skin graft area 7 on skin surface 8 of a patient 9. In this embodiment, the pad is held in place by. . .

DETDESC:

DETD(11)

Note . . . configuration of the grafted area. Due to the hydrostatic nature of the liquid silicone fill, the pressure transmitted to the graft tissue 7 by the tie-downs is distributed uniformly over the entire graft area.

DETDESC:

DETD(12)

Due to the clear transparent property of both the plastic envelope and